Supreme Court U.S.
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No.

In the Supreme Court of the United States

OCTOBER TERM, 1998

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

GREGORIA GRIJALVA, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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33pp

QUESTIONS PRESENTED

Before 42 U.S.C. 1395mm(g) was superseded, it authorized the Secretary of Health and Human Services to enter into contracts with private health maintenance organizations (HMOs) under which they received a fixed, per-person monthly fee for each Medicare beneficiary who chose to enroll in an HMO in place of traditional fee-for-services Medicare coverage. The HMO, in turn, was required to provide enrolled beneficiaries with all medical services covered by Medicare. Disputes between the HMO and the beneficiary regarding services were resolved by the Secretary or her agents.

The questions presented by this case are:

1. Whether the decision by a Section 1395mm(g) HMO to deny an enrolled Medicare beneficiary's request for health services constitutes government action subject to the requirements of the Due Process Clause of the Fifth Amendment.

2. Whether, in this nationwide class action, the district court properly issued an injunction, on due process grounds, imposing new procedural requirements that all HMOs that enroll Medicare beneficiaries under Section 1395mm(g) must follow and that the Secretary must enforce through Section 1395mm(g) contracts.

3. Whether, in light of Congress's enactment of new Medicare Part C, which eliminates the Secretary's authority to contract under Section 1395mm(g) and establishes a new "Medicare+Choice" program that provides greatly enhanced procedural protections for Medicare beneficiaries enrolled in HMOs, the judgments below should be vacated and the case remanded to the district court for further proceedings.

PARTIES TO THE PROCEEDINGS

The petitioner is Donna E. Shalala, Secretary, Health and Human Services. The respondents are plaintiffs Gregoria Grijalva, Carol Knox, Mary Lea, Beatrice Bennett, and Mildred Morrell, individuals and representatives of a class of persons similarly situated, and plaintiffs-intervenors Josephine Balistreri, Fred S. Scherz, Kevin A. Driscoll, Mina Ames, Edmundo B. Cardenas, Arline T. Donoho, Patricia Sloan, Beth Robley, Goldie M. Powell, and Richard Baxter.

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PETITION FOR A WRIT OF CERTIORARI

The Solicitor General, on behalf of Donna E. Shalala, Secretary of Health and Human Services, respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App. 1a-21a) is reported at 152 F.3d 1115. The opinion of the district court (App. 24a-58a) is reported at 946 F. Supp. 747.

JURISDICTION

The judgment of the court of appeals was entered on August 12, 1998. A petition for rehearing was denied on November 12, 1998. App. 22a-23a. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Relevant portions of the Medicare Act, as it existed when the district court ruled, 42 U.S.C. 1395mm, are reproduced in the Appendix to this petition, see App. 102a-109a, as are relevant provisions of the Balanced Budget Act of 1997, Pub. L. No. 105-33, §§ 4001-4002, 111 Stat. 275-330, see App. 70a-101a. Relevant portions of the Secretary's regulations implementing 42 U.S.C. 1395mm(g), as they existed at the time the district court ruled, 42 C.F.R. 417.608-417.638 (1996), are likewise set out in the Appendix, see App. 140a-149a, as are relevant provisions of the Secretary's current regulations, 63 Fed. Reg. 34,968 (1998), see App. 110a-139a.

STATEMENT

1. The Medicare program, established under Title XVIII of the Social Security Act, 42 U.S.C. 1395 *et seq.*, pays for covered medical care for eligible aged and disabled persons. Originally, Medicare operated exclusively in a manner similar to fee-for-service medical insurance. Under such arrangements, the beneficiary first obtains needed medical care. The beneficiary or his healthcare provider then submits a claim for reimbursement to the Medicare program. Claims are then reviewed by processing agents known as "fiscal intermediaries" or "carriers"—private companies that act under contract as the Secretary's fiscal agent to evaluate claims and determine whether payment is authorized by the Medicare statute. Where the fiscal intermediary or carrier approves the claim, it is paid by the federal government out of the Medicare Trust Funds in the Treasury. See generally *Regions Hosp.* v. *Shalala*, 118 S. Ct. 909, 912 (1998); *Schweiker* v. *McClure*, 456 U.S. 188 (1982).

In 1982, Congress added a provision to the Medicare Act to permit beneficiaries to obtain covered services in a fundamentally different way—by enrolling in private healthcare plans like health maintenance organizations (HMOs).

See Pub. L. No. 97-248, § 114(a), 96 Stat. 341, codified at 42 U.S.C. 1395mm. (Section 1395mm has now been superseded by new Medicare Part C, as discussed in greater detail below.) Because HMOs often operate efficiently and can obtain discounts for medical services from participating providers, they frequently can offer their enrollees a more comprehensive package of services—including extras like dental care—at the same or lower cost than the fee-for-service model.

To give Medicare beneficiaries the option of enrolling in HMOs at government expense, Section 1395mm authorized the Secretary to enter into two types of contracts with qualified HMOs. First, the Secretary could enter into a cost-based contract, under which Medicare reimbursed the HMO's reasonable costs (based on submitted reports) for services actually rendered to any Medicare beneficiary enrolled with the HMO. See 42 U.S.C. 1395mm(h); 42 C.F.R. 417.530-417.576 (1996). Second, the Secretary could enter into "risk-sharing" contracts, under which the HMO was paid a fixed monthly payment for each Medicare beneficiary who chose to enroll with the HMO; in return, the HMO was required to provide each enrollee with the full range of services covered by Medicare. 42 U.S.C. 1395mm(g). Under such risk-sharing contracts, the HMO bore the risks of increased patient needs, as Medicare did not adjust its monthly payments based on services actually used. Thus, such contracts were similar to HMO coverage purchased by individuals or by employers for their employees, as the HMO (and not the purchaser of the coverage) bore all costs associated with providing appropriate medical care. This case concerns only patients enrolled in risk-sharing HMOs, *i.e.*, HMOs that entered into contracts pursuant to 42 U.S.C. 1395mm(g).

Under 42 U.S.C. 1395mm, HMOs were required to provide "meaningful procedures for hearing and resolving grievances" between themselves and enrolled members.

42 U.S.C. 1395mm(c)(5)(A). Under the HHS regulations implementing Section 1395mm(c)(5)(A) that were before the district court, HMOs denying requests for medical services were required to notify beneficiaries of such decisions, give the reasons for denial, and notify beneficiaries of the right to ask the HMO to reconsider the decision. 42 C.F.R. 417.608 (1996). HMOs, however, had 60 days in which to issue such decisions, *ibid.*, as well 60 days in which to resolve reconsideration requests, *id.* § 417.620. Neither the statute nor the regulations provided an expedited decision mechanism for cases involving urgent medical needs. And neither the statute nor the regulations addressed the qualifications of HMO decisionmakers. HMO enrollees dissatisfied with adverse HMO decisions, however, could obtain reconsideration review by the HMO and the Secretary or her agents, *id.* §§ 417.614-417.626 (1996), and, subject to certain amount-in-controversy requirements, a hearing before an administrative law judge (ALJ) in the Department of Health and Human Services (HHS), followed by appeal to the Departmental Appeals Board (DAB) and judicial review. See 42 U.S.C. 1395mm(c)(5)(B); 42 C.F.R. 417.630-417.636 (1996). The HMO was required to be made a party to any hearing before an ALJ, and the HMO, if aggrieved by the ALJ's decision, also could seek review by the DAB and judicial review. 42 C.F.R. 417.632(c)(2), 417.634, 417.636 (1996).

2. Respondents have been certified as the named representatives of a nationwide class of Medicare-eligible individuals who enrolled in risk-based HMOs under Section 1395mm(g). See Order of July 18, 1995, C.A. E.R. 36; App. 25a n.1. They alleged that the HMOs were not providing adequate notice and appeal rights with respect to decisions to reduce or deny services. More effective procedures, they asserted, were required by Section 1395mm(c)(5)(A). They further claimed that initial HMO decisions constituted "state action" affecting constitutionally-protected property in-

terests, and that HMO decisions did not comport with the Due Process Clause.

a. The parties filed cross-motions for summary judgment, and the district partially granted respondents' motion, while denying the Secretary's motion. App. 24a-58a. The challenged HMO decisions, the court concluded, are properly attributable to the federal government, and HMO decisional processes therefore must comport with the Due Process Clause. *Id.* at 29a-34a. The court further held that the decisionmaking procedures then in effect did not afford respondents the process that was due under *Mathews* v. *Eldridge*, 424 U.S. 319 (1976). Among other things, the district court faulted the notices of decision issued by HMOs as difficult to understand, see App. 46a-50a, and criticized the time used to resolve urgent requests, *id.* at 43a-45a, 51a.

On March 3, 1997, the district court entered a mandatory injunction that imposed detailed new notice and hearing requirements. App. 59a-64a. Among other things, the injunction commands the Secretary to require that HMOs provide (in all but "exceptional circumstances") a written notice of any decision that denies, terminates or reduces services or treatment within "five working days" of an oral or written request for that care—without regard to whether the beneficiary would be adversely affected if the HMO took longer to resolve the matter. *Id.* at 60a. If the beneficiary seeks reconsideration of the decision, and the request is urgent, the HMO must issue a reconsideration decision within three working days. *Id.* at 62a. (The injunction provides no deadline for resolution of non-urgent reconsideration requests.) And where "acute care services" are at issue, the HMO must provide a hearing before denying the request; it may not discontinue such services until *after* the initial decision and the reconsideration process is completed. *Id.* at 63a. Any notice informing a beneficiary of any such decision, moreover, must be printed in 12-point type, specify

the basis for the decision, and advise the beneficiary of his appeal rights. *Id.* at 60a-61a.

The injunction further requires the Secretary to monitor and investigate compliance with all requirements, and bars the Secretary from contracting with, or renewing a contract with, any HMO that does not comply substantially with the notice and hearing requirements. App. 63a. The order specifies that the district court will retain jurisdiction over the case for a three-year period, and permits respondents to return to the court for additional relief if the order does not redress their claimed injuries. *Id.* at 64a.

b. The Secretary moved the district court to stay its injunction pending appeal, and the district court granted the motion. App. 65a-69a. In seeking the stay, the Secretary pointed out that on April 30, 1997—just after the district court entered its injunction—the Secretary had issued new HMO regulations in interim final form. See 62 Fed. Reg. 23,368 (1997). The Secretary noted that those regulations made several significant changes in notice and appeal procedures. Among other things, the revised regulations provided a new procedure for expedited review in urgent cases: Although HMOs would have 60 days within which to make ordinary determinations, they would have only 72 hours to make decisions where delay could seriously jeopardize the beneficiary's life, health, or functioning. See *id.* at 23,370-23,371; see also *id.* at 23,375 (adding 42 C.F.R. 417.608, 417.609). The district court concluded that a stay was warranted, reasoning that "the hardships faced by the Plaintiffs outweigh those of the Defendant, but that the entire case may become largely moot if the Secretary's attestations regarding rule changes * * * are implemented without delay." App. 68a.

3. The Secretary appealed the district court's March 3, 1997 Order. While the appeal was pending, Congress (on August 5, 1997) overhauled Medicare's statutory structure with respect to HMOs as part of the Balanced Budget Act of

1997 (BBA), Pub. L. No. 105-33, §§ 4001-4002, 111 Stat. 275-330. See App. 70a-101a (reproducing relevant portions).

a. To replace Section 1395mm(g), the BBA creates new Part C of the Medicare Act and establishes the "Medicare+ Choice" program. "Medicare+Choice" is designed to offer beneficiaries a widely expanded choice of alternatives to traditional fee-for-service Medicare. Those options include participation in HMOs and other private managed-care and fee-for-service plans at government expense, and a new medical savings account option. See 111 Stat. 276 (Section 1851(a)(2), to be codified at 42 U.S.C. 1395w-21(a)(2)); H.R. Conf. Rep. No. 217, 105th Cong., 1st Sess. 585 (1997). The new law directs the Secretary to implement the Medicare+ Choice program by establishing a process through which Medicare beneficiaries can, at their option, have the Secretary acquire coverage for them through participating private healthcare organizations in place of original fees-for-services Medicare. 111 Stat. 278 (Section 1851(c)(1), to be codified at 42 U.S.C. 1395w-21(c)(1)). HMOs may not accept Medicare beneficiaries as enrollees and may not receive payments under the program absent a valid Medicare+ Choice contract with the Secretary. See 111 Stat. 319 (Section 1857(a), to be codified at 42 U.S.C. 1395w-27(a)).

Part C provides an enhanced statutory framework—an entire Section entitled "Benefits and Beneficiary Protections"—to govern such issues as quality assurance, disputes over treatment, grievances and appeals. See 111 Stat. 293 (Section 1852(g), to be codified at 42 U.S.C. 1395w-22(g)). As before, HMOs must in the first instance determine for themselves whether they believe that a requested treatment is appropriate (just as they would with respect to non-Medicare enrollees). But, as a condition of participation, HMOs must provide Medicare enrollees with a prompt, clear, and understandable statement concerning adverse decisions. 111 Stat. 293 (Section 1852(g)(1), to be codified at 42 U.S.C. 1395w-22(g)(1)). As before, an enrollee

dissatisfied with such a decision may seek reconsideration. But, unlike the statute before the district court, which did not prescribe a deadline for reconsideration decisions, the new statute requires HMOs to issue reconsideration decisions within 60 days (or earlier if the Secretary so directs). 111 Stat. 293 (Section 1852(g)(2)(A), to be codified at 42 U.S.C. 1395w-22g(2)(A)). Moreover, unlike the statute and regulations that were the subject of the district court's decision, the new statute contains expedition provisions that require HMOs to issue decisions "not later than 72 hours [after] receipt of the request for the determination or reconsideration" in urgent cases. 111 Stat. 294 (Section 1852(g)(3)(B), to be codified at 42 U.S.C. 1395w-22(g)(3)(B)).

Unlike the prior statute and regulations, the new statute also addresses the qualifications of the HMO reconsideration decisionmaker. In particular, where the basis for the initial decision to reduce or deny services is lack of medical necessity, the reconsideration decision must be made by an HMO physician with "appropriate expertise in the [relevant] field of medicine." 111 Stat. 293 (Section 1852(g)(2)(B), to be codified at 42 U.S.C. 1395w-22(g)(2)(B)). In addition, the physician addressing the reconsideration request may not be the same physician who made the initial decision. *Ibid.*

All private HMO reconsideration decisions denying or reducing services are subject to review by a neutral, independent entity selected by the Secretary. 111 Stat. 294 (Section 1852(g)(4), to be codified at 42 U.S.C. 1395w-22(g)(4)). Any enrollee (but not an HMO) dissatisfied with the result of the determination of the independent entity may seek a hearing before an ALJ in HHS if the amount in controversy exceeds $100, and the HMO becomes a party to any such hearing. 111 Stat. 294 (Section 1852(g)(5), to be codified at 42 U.S.C. 1395w-22(g)(5)). ALJ decisions are subject to review by the DAB and, if the amount remaining in controversy after administrative review exceeds $1000,

either the HMO or the beneficiary may (if aggrieved) seek judicial review of the agency's decision. *Ibid.*

New Medicare Part C also provides the Secretary with substantial enforcement authority, including the ability to impose monetary penalties and to terminate contracts with HMOs that fail to comply with statutory or regulatory requirements. See 111 Stat. 323-325 (Section 1857(g) and (h), to be codified at 42 U.S.C. 1395w-27(g) and (h)). The new procedures also provide the Secretary with substantial flexibility. Although the district court and the court of appeals read Section 1395mm(c) as barring the Secretary from contracting (or renewing a contract) with any HMO that failed substantially to comply with Medicare requirements, see App. 19a-20a, 54a (citing 42 U.S.C. 1395mm(c)), the new law omits the language upon which those courts relied and does not otherwise provide that termination is a mandatory consequence of non-compliance.[1]

Finally, the new law eliminates the Secretary's authority to renew risk-sharing contracts under Section 1395mm(g)—the principal statutory provision at issue in the district court—as of January 1, 1999. 111 Stat. 328 (amending Section 1876 by adding new subsection (k)(1), to be codified at 42 U.S.C. 1395mm(k)(1)).[2] We have been informed by HHS

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[1] Section 1395mm(c)(1) provided that "[t]he Secretary *may not* enter into a contract under this section with an eligible organization unless it meets the requirements of this subsection." (emphasis added). The new law merely provides that the Secretary's contracts with healthcare organizations under the Medicare+Choice program "shall provide that the organization agrees to comply with the applicable requirements and standards of [Part C] and the terms and conditions of payment as provided for in [Part C]." 111 Stat. 319 (Section 1857(a), to be codified at 42 U.S.C. 1395w-27(a)).

[2] New subsection (k)(1) states that, "on or after the date standards for Medicare+Choice organizations and plans are first established * * *, the Secretary shall not enter into any risk-sharing contract under this section," and further provides that "for any contract year beginning on or

that all risk-sharing contracts entered into under Section 1395mm(g) expired effective December 31, 1998, and that no such contracts were renewed for 1999.[3]

b. On June 26, 1998—while the appeal to the Ninth Circuit was still pending—the Secretary issued interim final regulations implementing the new Medicare Part C Medicare+Choice program. See 63 Fed. Reg. at 34,968 (relevant portions reproduced at App. 110a-139a). The regulations became applicable on January 1, 1999, at the beginning of the initial contracting cycle for Medicare+Choice HMOs. See 63 Fed. Reg. at 34,968, 34,969, 34,976, 52,610.

Building on new Medicare Part C's enhanced statutory protections for Medicare beneficiaries, the Secretary's regulations require participating HMOs to issue prompt and understandable initial decisions and reconsideration decisions. While the BBA provides no statutory deadline for initial HMO decisions, and the Section 1395mm regulations before the district court allowed delays of up to 60 days, the Secretary's new regulations require HMOs to make initial decisions in non-urgent cases "as expeditiously as the [beneficiary's] health condition requires, but no later than 14 calendar days after the date the organization receives the request." 63 Fed. Reg. at 35,108 (adding 42 C.F.R. 422.568(a)). While the BBA (like the regulations before the district court) sets 60 days as the maximum time limit for resolution of ordinary reconsideration requests, the Secretary's new regulations now require that such decisions be made within 30 days in non-urgent cases. *Id.* at 35,110

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after January 1, 1999, the Secretary shall not renew any such contract." 111 Stat. 328 (to be codified at 42 U.S.C. 1395mm(k)(1)).

[3] We have been informed by HHS that it granted a temporary extension of a Section 1395mm(g) contract with a New Jersey HMO that became insolvent and is currently being operated by the State. The temporary extension—which proved necessary to permit a transition of enrollees to new, qualifying Medicare+Choice plans or traditional fee-for-service Medicare—will not extend beyond February 28, 1999.

(adding 42 C.F.R. 422.590(a)(2)). Finally, all HMO notices informing enrollees of denials of requested services must, among other things, state "the specific reasons for the denial in understandable language," and inform enrollees of their reconsideration and appeal rights. *Id.* at 35,108 (adding 42 C.F.R. 422.568(d)(1)); see also 111 Stat. 293 (Section 1852(g)(1) (B), to be codified at 42 U.S.C. 1395w-22(g)(1)(B)). The regulations before the district court, in contrast, required a statement of reasons, but did not specifically require that it be understandable to ordinary people. 42 C.F.R. 417.608 (1996); see also App. 46a-50a (criticizing prior HMO notices).

Unlike the Section 1395mm regulations the district court found inadequate, the new Medicare+Choice regulations also address the need for expedition in urgent cases. Consistent with the BBA itself, the Medicare+Choice regulations provide that, where delays may threaten the beneficiary's health, HMOs must make initial and reconsideration decisions within 72 hours of the relevant request. See 63 Fed. Reg. at 35,108-35,109 (adding 42 C.F.R. 422.572 pertaining to initial decisions); *id.* at 35,110 (adding 42 C.F.R. 422.590(d) pertaining to reconsideration). Moreover, where an enrollee is receiving authorized in-patient hospital care, the Secretary's new regulations provide that the HMO may not decide that the care is unnecessary absent the concurrence of the physician responsible for the in-patient treatment. *Id.* at 35,112 (adding 42 C.F.R. 422.620(b)). Even then, the enrollee may seek immediate review by an independent peer review organization, and the care may not be discontinued until that organization issues its decision. *Id.* at 35,112-35,113 (adding 42 C.F.R. 422.622).

The new regulations address other aspects of the HMO decisional process as well. Among other things, they require HMOs to afford enrollees seeking reconsideration "a reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well

as in writing." 63 Fed. Reg. at 35,110 (adding 42 C.F.R. 422.586). And, implementing the BBA, they provide that reconsideration decisions must be made by qualified medical personnel in appropriate circumstances, and by personnel other than the individuals who made the initial decision. *Id.* at 35,111 (adding 42 C.F.R. 422.590(g)(1) and (2)).[4]

4. On August 12, 1998—after enactment of the new Medicare Part C, and after the Secretary's issuance of implementing regulations—the court of appeals affirmed the judgment of the district court. App. 1a-21a. The court of appeals declined to consider the case in light of the intervening revisions to the regulations that had been before the district court. See *id.* at 20a. Instead, the court of appeals addressed the case as if the original regulations before the district court were still in place.[5]

The court of appeals held that a private HMO's decision to reduce or deny services constitutes government action. The court explained that, to establish government action, the plaintiff must show that "there is a sufficiently close nexus between the State and the challenged action of the regulated

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[4] The statute and regulations also provide mechanisms for monitoring and enforcing HMO compliance with grievance and appeal requirements. The statute, for example, requires HMOs to establish and maintain provisions for monitoring and evaluating both clinical and administrative aspects of health plan operations, and the regulations make clear that such "quality assurance" programs must monitor and evaluate the grievance and appeal process. See 111 Stat. 291 (Section 1852(e), to be codified at 42 U.S.C. 1395w-22(e)); 63 Fed. Reg. at 35,082 (adding 42 C.F.R. 422.152). In addition, an HMO's failure to comply substantially with appeal and grievance provisions is potentially a ground for terminating its contract. *Id.* at 35,104 (adding 42 C.F.R. 422.510).

[5] The statutory amendments were enacted shortly before the government filed its reply brief in the court of appeals. The government accordingly informed the Court that the statute would later modify the requirements for HMO grievance and appeal procedures, but that it had not yet taken effect and therefore did not, at that time, bear on the issues presented. See Gov't C.A. Reply Br. 10 n.9.

entity so that the action of the latter may be fairly treated as that of the State itself." App. 8a (quoting *Blum* v. *Yaretsky*, 457 U.S. 991, 1004 (1982)). It further noted that, while government regulation is not by itself sufficient to attribute private action to the government, "[g]overnment action exists if there is a symbiotic relationship with a high degree of interdependence between the private and public parties such that they are 'joint participant[s] in the challenged activity.'" *Id.* at 8a-9a (quoting *Burton* v. *Wilmington Parking Auth.*, 365 U.S. 715, 725 (1961)).

Applying those standards, the court held that "HMOs and the federal government are essentially engaged as joint participants to provide Medicare services such that the actions of HMOs in denying medical services to Medicare beneficiaries and in failing to provide adequate notice may fairly be attributed to the federal government." App. 9a-10a. The Ninth Circuit reasoned that the Secretary "extensively regulates the provision of Medicare services by HMOs"; the HMOs must "comply with all federal laws and regulations"; the Secretary pays HMOs "for each enrolled Medicare beneficiary (regardless of the services provided)"; and the "federal government has created the legal framework—the standards and enforcement mechanisms—within which HMOs" must operate. *Id.* at 10a. The court of appeals rejected the Secretary's argument that HMO decisions to deny or reduce treatment are private determinations, made without government compulsion or influence. It held that, in this context, such decisions "are more accurately described as * * * interpretations of the Medicare statute" rather "than * * * * medical judgments," and thus could be properly attributed to the government. *Id.* at 11a. Turning to the due process question, the court of appeals held that, under the balancing test established by *Mathews* v. *Eldridge*, 424 U.S. 319 (1976), the process HMOs provided to Medicare beneficiaries under Section 1395mm and the Secretary's pre-April 1997 regulations was less than their

constitutional due, largely for the reasons given by the district court. App. 12a-18a.

The court of appeals also rejected the Secretary's challenge to the nature and scope of the injunctive remedy imposed. Because Congress had delegated implementation of Section 1395mm to the Secretary, she argued that the district court should have remanded the matter to her for an expedited rulemaking to cure the identified ills; and she disputed the appropriateness of the district court's three-year injunction, which prescribed detailed deadline, notice, hearing, and proceeding requirements. The Ninth Circuit declined to afford any deference to the Secretary's views of appropriate process, App. 13a n.3, and rejected her request for a remand, *id.* at 18a & n.4.

5. The Secretary sought rehearing and rehearing en banc. The petition emphasized that the new statute and implementing regulations contain substantially different and more detailed hearing and grievance procedures than those considered in the panel's decision. It asserted that the court's holding, by effectively "constitutionalizing" HMO decisions, impaired the ability of Congress and the Secretary to tailor procedural safeguards to the complex and varied relations between HMOs and their patients. And it urged the court of appeals either to rehear the case or to vacate the injunction and remand the matter to the district court with instructions to consider the new statute and implementing regulations. Gov't Pet. for Reh'g 9-19. The court of appeals denied the petition. App. 22a-23a.

REASONS FOR GRANTING THE PETITION

Affirming the district court's issuance of a detailed and highly prescriptive nationwide injunction, the Ninth Circuit in this case held (1) that Health Maintenance Organizations and similar healthcare organizations (HMOs) engage in government action when they deny Medicare enrollee requests for services, and (2) that the HMO procedures

required by the Secretary's now statutorily-superseded regulations under 42 U.S.C. 1395mm were insufficient to meet the requirements of due process. Those rulings and their practical consequences are of broad significance in the administration of the Medicare Program and ordinarily would warrant plenary review by this Court. The legal issues presented by this case, however, are similar to those before this Court in *American Manufacturers Mutual Insurance Co., et al.* v. *Sullivan, et al.*, No. 97-2000 (argued Jan. 19, 1999). Accordingly, we suggest that the petition in this case be held pending the Court's decision in *Sullivan*.

Moreover, shortly after the district court ruled in this case, Congress comprehensively revised Medicare's treatment of HMOs by enacting an entirely new Part C of the Medicare Act, introducing the new Medicare+Choice program. Those new provisions, and the Secretary's regulations implementing them, provide dramatically greater procedural protections for beneficiaries who choose to enroll in HMOs; they eliminate the asserted defects that prompted the request for judicial relief in this case; and they deprive 42 U.S.C. 1395mm(g), upon which the district court and the court of appeals relied, of any future effect. As a result of those changes, the challenge to the regulations adjudicated by the district court and court of appeals is now moot. Accordingly, we ask that, after holding the petition pending this Court's decision in *Sullivan*, the Court vacate the judgment of the court of appeals and remand the case with directions to (1) vacate the judgment of the district court and (2) remand the case to that court for consideration of any challenges respondents might raise to the new statute and its implementing regulations in light of the decision in *Sullivan*.

A. The Petition Should Be Held Pending This Court's Decision In *American Manufacturers Mutual Insurance Co., et al.* v. *Sullivan, et al.*, No. 97-2000 (Argued Jan. 19, 1999)

Government action and due process questions similar to those raised in this case are currently before the Court in *American Manufacturers Mutual Insurance Co., et al.* v. *Sullivan, et al.*, No. 97-2000 (argued Jan. 19, 1999). There, the Third Circuit held that payment decisions made by workers' compensation insurers, as permitted by state law, were both attributable to the State and inconsistent with due process. See *Sullivan* v. *Barnett*, 139 F.3d 158 (1998).

The court of appeals decisions in *Sullivan* and in this case are remarkably similar on the government action issue. Neither decision examines the "three principles" identified by this Court for determining whether otherwise private conduct "is governmental in character": (1) "the extent to which the actor relies on governmental assistance," or accedes to the government's coercive powers or encouragement, in effectuating its will, (2) "whether the actor is performing a traditional governmental function," and (3) "whether the injury caused is aggravated in a unique way by the incidents of governmental authority." *Edmonson* v. *Leesville Concrete Co.*, 500 U.S. 614, 621-622 (1991); see also *Blum* v. *Yaretsky*, 457 U.S. 991, 1004 (1982) (government "normally can be held responsible for a private decision only when it has exercised coercive power or has provided such significant encouragement * * * that the choice must in law be deemed to be that of the [government]"). Rather, both predicate a finding of government action largely on the government's regulatory role. Compare *Sullivan*, 139 F.3d at 168, with App. 9a-10a.

In concluding that medical treatment decisions by private HMOs concerning their Medicare-beneficiary members are properly attributed to the federal government, the Ninth Circuit appears to have relied primarily on the "rather vague

generalization," *Blum*, 457 U.S. at 1010, that there was a "high degree of interdependence" and a "symbiotic relationship," App. 9a, that made the government "a joint participant in the challenged activity." *Burton* v. *Wilmington Parking Auth.*, 365 U.S. 715, 725 (1961). The facts the Ninth Circuit relied upon for that conclusion, however, are largely common to heavily regulated industries. See App. 10a (relying on the facts that the "Secretary extensively regulates," that "HMOs are required * * * to comply with all federal laws," that the Secretary is obligated to ensure that "HMOs provide * * * meaningful * * * procedures," that the "federal government has created the legal framework," and that the Secretary has adjudicatory authority with respect to HMO decisions). Compare *Jackson* v. *Metropolitan Edison Co.*, 419 U.S. 345, 357 (1974); see *id.* at 350.

Significantly here, the relationship between an HMO and its Medicare-beneficiary members is the product of a private choice by those members. Medicare beneficiaries may choose among providers and forms of coverage, and the government neither requires them to enroll in an HMO nor precludes them from disenrolling. In this respect, the HMO's relationship with its Medicare-beneficiary members resembles its relationship with members who elect HMO coverage under employer-sponsored or other private health plans. With respect to each, the HMO simply determines what treatment is appropriate under its professional and contractual obligations, without government participation or assistance.[6] And although money is paid out of the Medicare

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[6] Indeed, the first sentence of the Medicare statute prohibits the "exercise [of] any" governmental "supervision or control over the practice of medicine or the manner in which medical services are provided." 42 U.S.C. 1395. In *Blum* v. *Yaretsky*, the Court held that the exercise of ordinary medical judgment is not state action, even where it may affect eligibility for government benefits. Although the Ninth Circuit sought to distinguish *Blum* by characterizing HMO determinations as more in the nature of interpretations of the Medicare Act, rather than medical

Trust Funds to cover the flat monthly rate charged for the Medicare beneficiary's enrollment in the HMO, the financial consequences of a determination by the HMO to furnish or deny particular services to that beneficiary once he has enrolled are borne by the HMO alone.[7]

On the merits of the due process issue, the Ninth Circuit rejected the Secretary's contention that her view of the appropriate and meaningful procedures should be accorded substantial weight, declaring that there is "nothing in *Mathews* v. *Eldridge* or subsequent cases to suggest that such is necessary or advisable." App. 13a n.3. That was error. The Court expressly stated in *Mathews* v. *Eldridge*, 424 U.S. 319, 349 (1976), that, "[i]n assessing what process is due * * *, substantial weight must be given to the good-faith judgments of the individuals charged by Congress with the administration of social welfare programs that the proce-

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judgments, see App. 11a, the primary criterion employed by HMOs in this context—whether medical services are "reasonable and necessary," 42 U.S.C. 1395y(a)—essentially requires an exercise of medical, not legal judgment. The complaint in this case, moreover, demonstrates that the named respondents seek to challenge medical judgments. C.A. E.R. 10-11, ¶ 29 (physical therapy denied because patient could not follow therapeutic directions), 12-13, ¶¶ 40-41 (failure to prescribe adequate pain medication or order physical therapy), 13-15, ¶¶ 48-54 (skilled nursing care found not medically necessary), 16, ¶ 62 (speech therapy denied because it would not be effective).

[7] In *Blum*, the Court rejected the contention that decisions made by physicians and nursing homes were attributable to the State, despite "state subsidization of the operating and capital costs of the facilities" and coverage for "the medical expenses of more than 90% of the patients." 457 U.S. at 1011. That the government pays for coverage neither encourages HMOs to deny requests for treatment, nor prevents the financial impact of HMO decisions from being visited exclusively on the HMO. If the fact that the government pays for coverage were a sufficient basis for attributing HMO conduct to the government, HMOs providing services to government employees under the Federal Employees Health Benefits Act of 1959, 5 U.S.C. 8901 *et seq.*, would also all be government actors.

dures they have provided assure fair consideration." For similar reasons, the imposition of a detailed judicial injunction providing new requirements, rather than a remand order directing the Secretary to promulgate new procedures through a participatory and fully public rulemaking process, was error as well. Congress delegated implementation of 42 U.S.C. 1395mm(g) and the creation of "meaningful" procedures in the first instance to the Secretary, not to the courts. Cf. *SEC* v. *Chenery Corp.*, 332 U.S. 194, 199 (1947) (where agency action is set aside, "the [agency is] bound to deal with the problem afresh, performing the function delegated to it by Congress"); *Florida Power & Light Co.* v. *Lorion*, 470 U.S. 729, 744 (1985) (proper course where agency errs is to "remand to the agency").[8]

The arguments that the *Sullivan* petitioners make in support of reversal there apply with equal force in this case as well.[9] Indeed, so closely related are the cases that lead

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[8] The district court also exceeded its authority in ordering the Secretary to terminate contracts with HMOs that fail to comply with the procedures it imposed. See *Blessing* v. *Freestone*, 520 U.S. 329, 343-344 (1997).

[9] See 97-2000 Pet. Br. 20-21 (arguing that State does not influence insurer's non-payment decision), 17-22 (arguing that insurer decisions are not governmental benefits determinations), 22-25 (no unique aggravation of injury by government), 26-32 (regulated nature of industry does not render private action attributable to State). And there are clear similarities between the due process arguments as well. For example, in this case the lower courts implicitly concluded that respondents could have a constitutionally-protected property interest in receiving Medicare services *before* their legal entitlement to those services was established, and that pre-deprivation processes were required in certain contexts, App. 63a. Petitioners in *Sullivan* challenge similar conclusions reached by the court of appeals there. See 97-2000 Pet. Br. 35-38 (arguing that due process does not apply to disputed applications for treatment where the legal entitlement to the treatment, and thus a property interest therein, has not been established), 42-44 (arguing that pre-deprivation process is not required); see also *Lyng* v. *Payne*, 476 U.S. 926, 942 (1986) (noting that

counsel in this case filed an amicus brief in *Sullivan*, emphasizing the potential impact of the Court's decision there on the Medicare program at issue here.[10] For the foregoing reasons, we suggest that the petition in this case be held pending the decision in *Sullivan*.

B. The Judgments Below Should Be Vacated And The Case Remanded To The District Court For Consideration Of Intervening Statutory and Regulatory Changes

Absent the obvious similarities between this case and *Sullivan*, the Ninth Circuit's decision in this case ordinarily would warrant plenary review by this Court at the present time. It declares unconstitutional the Secretary's implementation of a major federal statutory program; it affirms a detailed nationwide injunction requiring the Secretary to impose certain procedures on participating HMOs; and it constitutionalizes on a nationwide basis the conduct of hundreds of private healthcare organizations offering services to millions of individuals.

On August 5, 1997, however, Congress comprehensively reformed this area of law—enacting the new Medicare Part C and establishing the new "Medicare+Choice" program. See Balanced Budget Act of 1997, Pub. L. No. 105-33, §§ 4001-4002, 111 Stat. 275-330. The new statute and the Secretary's regulations promulgated thereunder dramatically expand the procedural and substantive protections afforded to Medicare beneficiaries who choose to enroll in private HMOs. Indeed, Congress gave specific attention to the procedures it considered necessary to protect beneficiary

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the Court has not resolved whether "applicants for benefits, as distinct from those already receiving them, have a legitimate claim of entitlement protected by the Due Process Clause").

[10] See 97-2000 Amici Curiae American Association of Retired Persons, The Center For Medicare Advocacy, Inc., *et al.*, Br. at 4, 7.

rights, enacting a section of new Medicare Part C entitled "Benefits and Beneficiary Protections." 111 Stat. 286 (Section 1852, to be codified at 42 U.S.C. 1395w-22). Consequently, the new statute and the implementing regulations it required the Secretary to promulgate now separately address the alleged deficiencies identified by the lower courts. See pp. 7-12, *supra*. Among other things, they specifically require HMOs to issue understandable notices of decision, 111 Stat. 293 (Section 1852(g)(1), to be codified at 42 U.S.C. 1395w-22(g)(1)); 63 Fed. Reg. 35,108 (1998) (adding 42 C.F.R. 422.568(d)); they provide that medical necessity decisions must be made by qualified medical personnel, 111 Stat. 293 (Section 1852(g)(2)(B), to be codified at 42 U.S.C. 1395w-22(g)(2)(B)); 63 Fed. Reg. at 35,111 (adding 42 C.F.R. 422.590(g)(2)); and they mandate prompt initial decisions (within 14 days) and reconsideration decisions (within 30 days) in all cases, and expedited decisions (within 72 hours) if delay could jeopardize the health of the beneficiary. 63 Fed. Reg. at 35,108-35,110 (adding 42 C.F.R. 422.568(a), 422.572, 422.590(a)-(d)); 111 Stat. 293-294 (Section 1852(g)(2) and (3), to be codified at 42 U.S.C. 1395w-22(g)(2) and (3)).[11] Moreover, HMO determinations adverse to the enrollee are subject to automatic review by an independent third party acting as the Secretary's agent, 111 Stat. 294 (Section 1852(g)(4), to be codified at 42 U.S.C. 1395w-22(g)(4)); 63 Fed. Reg. at 35,111 (adding 42 C.F.R. 422.592), and dissatisfied beneficiaries may obtain a hearing before an ALJ

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[11] The district court's concern that HMO physicians might face disincentives to assisting enrollees in pursuing their requests, App. 49a; see *id.* at 62a (enjoining HMO retaliation against healthcare providers), is addressed by the new statute and regulations as well. See 111 Stat. 295 (Section 1852(j)(3), to be codified at 42 U.S.C. 1395w-22(j)(3)); see, *e.g.*, 63 Fed. Reg. at 35,108 (adding 42 C.F.R. 422.570(f)) (barring punitive action against physician for assistance in requesting expedition).

and judicial review, as provided in and subject to the limits set forth in the statute. See pp. 8-9, *supra*.[12]

The legal regime that respondents challenged and the district court and Ninth Circuit reviewed thus has been superseded by a new statutory framework and new regulations fleshing out that framework. No court has passed on the constitutional sufficiency of the new procedures or their implementation. As a result, the law has "been sufficiently altered" pending appeal "so as to present a substantially different controversy than the one the [lower courts] originally decided." *Northeastern Fla. Chapter of the Associated Gen. Contractors* v. *City of Jacksonville*, 508 U.S. 656, 662 n.3 (1993); *id.* at 670-671 (O'Connor, J., dissenting). See also App. 66a (district court recognition that "on appeal much of the March 3, 1997 Order might be moot" because "of other efforts on the part of state and federal legislatures [to] address[] the same issues addressed by this Court"); see also *id.* at 68a ("the entire case may become largely moot" if even the April 1997 rule changes were "implemented without delay").

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[12] Although these new provisions address most areas covered by the district court's injunction, they take a fundamentally different approach to several key issues. For example, the Secretary's expedition provisions are more favorable to beneficiaries inasmuch as they require reconsideration decisions within three calendar days, see p. 11, *supra*, whereas the district court's order requires such decisions in three working days, App. 62a. While the district court required that detailed written notices of initial decisions be provided within five days even where the beneficiary's health is not in imminent jeopardy, and Congress specified no specific time frame in such cases, see H.R. Conf. Rep. No. 217, 105th Cong, 1st Sess. 605 (1997) (noting that Congress left that issue to the Secretary), the Secretary selected a 14-day deadline, 63 Fed. Reg. at 35,108 (adding 42 C.F.R. 422.568(a)). Finally, although the Secretary has required certain inpatient hospital services to continue during the pendency of an administrative appeal, she did not extend similar requirements to a broad, unspecified range of "acute care" services. Compare 63 Fed. Reg. at 35,112-35,113 (adding 42 C.F.R. 422.620(b), 422.622), with App. 63a.

Under circumstances such as these, the Court has "set aside the judgment of the Court of Appeals with direction to enter a new judgment setting aside the order of the District Court and remanding to that court for such further proceedings as may be appropriate in light of the supervening event." *McLeod* v. *General Electric*, 385 U.S. 533, 535 (1967) (per curiam); see, *e.g.*, *Calhoun* v. *Latimer*, 377 U.S. 263, 264 (1964) (per curiam) ("vacat[ing] the judgment and remand-[ing] the cause to the District Court for further proceedings" to consider "the nature and effect" of a supervening change in school board policy); *Heckler* v. *Lopez*, 469 U.S. 1082 (1984) (mem.) (vacating judgment and remanding case "to the * * * Court of Appeals * * * to be remanded to the * * * District Court" for appropriate action in light of new legislation); see also *United States Dep't of the Treasury* v. *Galioto*, 477 U.S. 556, 559-560 (1986) (vacating judgment on direct appeal and remanding to district court because a new "enactment significantly alter[ed] the posture of th[e] case"). As the Court explained in *Lewis* v. *Continental Bank Corp.*, 494 U.S. 472, 482 (1990), "in instances where mootness is attributable to a change in the legal framework governing the case, and the plaintiff may have some residual claim under the new framework that was understandably not asserted previously, our practice is to vacate the judgment and remand for further proceedings in which the parties may, if necessary, amend their pleadings or develop the record more fully."

In fact, it may be that the new statute renders moot not merely the appeal, but the entire case as well. Certainly the subject matter on which the district court and the Ninth Circuit focused their analysis—Section 1395mm(g), the Secretary's implementing regulations, and HMO conduct thereunder, see App. 35a-40a, 46a-50a (district court); *id.* at 3a-5a, 13a (court of appeals)—no longer forms a legitimate basis for judicial relief. The new statute eliminates the Secretary's authority to enter into risk-sharing contracts

under Section 1395mm(g), and no such contracts were renewed for 1999. See pp. 9-10, & nn.2-3, *supra*. As a result, the regulations and notice and appeal procedures that the district court found inadequate are without force or effect; the protections required by the new Medicare Part C and Medicare+Choice control instead. *Princeton Univ.* v. *Schmid*, 455 U.S. 100, 103 (1982) (per curiam) (where "the regulation at issue is no longer in force" and the "lower court's opinion" does not "pass on the validity of the revised regulation," the "case has lost its character as a present, live controversy of the kind that must exist if we are to avoid advisory opinions on abstract questions of law").[13] Moreover, the conduct that respondents challenged and the lower courts found unconstitutional (*e.g.*, the allegedly inadequate notice and time limits) are now addressed by the new statute and regulations. See *Associated General Contractors*, 508 U.S. at 663 n.3 (cases moot where "the statutes at issue * * * were changed substantially, and * * * there was therefore no basis for concluding that the challenged conduct

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[13] The change in the statute, moreover, eliminates the district court's and the court of appeals' rationale—their *ratio decidendi*—for prohibiting the Secretary from entering into or renewing a contract with *any* HMO that violates the procedural requirements those courts believed to be required by Section 1395mm. See App. 63a. To justify that prohibition, the district court and court of appeals both relied on Section 1395mm(c)(1)'s declaration that "[t]he Secretary *may not* enter into a contract under this section with an eligible organization unless it meets the requirements of this subsection." *Id.* at 20a, 54a (quoting 42 U.S.C. 1395mm(c)(1)). See also *id.* at 54a-55a (justifying additional procedural requirements by declaring that the Secretary's failure to impose them in her HMO contracts is a "violation of 42 U.S.C. § 1395mm(c)(1)"); *id.* at 55a-56a (similar). The BBA, however, omits the prohibitory language of Section 1395mm(c)(1) upon which those courts relied, and nowhere suggests that termination and non-renewal are mandatory consequences of HMO non-compliance. See p. 9 & n.1, *supra*. It thus wholly eliminates the statutory provision upon which both lower courts expressly rested their remedial decisions.

was being repeated"); *Bowen* v. *Kizer*, 485 U.S. 386, 387 (1988) (per curiam) (new legislation that provides relief sought by the plaintiffs renders lawsuit moot).[14]

Of course, if the entire case (rather than just the appeal) were indisputably moot, the proper disposition would be to remand the case with a direction that the complaint be dismissed. *United States* v. *Munsingwear, Inc.*, 340 U.S. 36, 39-40 (1950). Given the possibility that the district court may need to dispose of residual claims on remand, see, *e.g.*, C.A. E.R. 21 (request for attorney's fees), and because respondents might seek to amend their complaint to challenge the constitutionality of the new statute and the regulations implementing the new statute, see, *e.g.*, *Calhoun*, 377 U.S. at 264; *Lewis*, 494 U.S. at 482, the Court should neither direct nor preclude dismissal but rather permit the district court to conduct such "further proceedings as may be appropriate in light of" the statutory and regulatory reforms. *McLeod*, 385 U.S. at 535. See also *Burlington Truck Lines, Inc.* v. *United States*, 371 U.S. 156, 172 (1962) (when confronted with intervening facts, court of appeals should not review administrative agency decision but should vacate order and remand to agency for further consideration in light of changed conditions). The district court could then undertake any such further proceedings in light of both the new statute and the new regulations as well as this Court's decision in *Sullivan*.

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[14] See also *United Transp. Union* v. *State Bar*, 401 U.S. 576, 584 (1971) ("An injunction can issue only after the plaintiff has established that the conduct sought to be enjoined is illegal and that the defendant, if not enjoined, will engage in such conduct."); *Legal Assistance for Vietnamese Asylum Seekers* v. *Department of State*, 45 F.3d 469, 472 (D.C. Cir. 1995) (Plaintiffs are "certainly not entitled to prospective relief based on a no longer effective version of a later amended regulation.").

CONCLUSION

The Court should hold the petition for a writ of certiorari pending the decision in *American Manufacturers Mutual Insurance Co., et al.* v. *Sullivan, et al.*, No. 97-2000 (argued Jan. 19, 1999). The Court should then grant the petition for a writ of certiorari, vacate the judgment of the court of appeals, and remand to the court of appeals with instructions to (1) vacate the judgment of the district court and (2) remand the case to the district court for consideration of Sections 4001 and 4002 of the Balanced Budget Act of 1997 and the regulations of the Secretary of Health and Human Services implementing those provisions in light of the Court's decision in *Sullivan*.

Respectfully submitted.

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FEBRUARY 1999

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No.

In the Supreme Court of the United States

OCTOBER TERM, 1998

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

GREGORIA GRIJALVA, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

APPENDIX TO PETITION FOR A WRIT OF CERTIORARI

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APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 97-15877

GREGORIA GRIJALVA; CAROL KNOX; MARY LEA; BEATRICE BENNETT; AND MILDRED MORRELL, INDIVIDUALS AND REPRESENTATIVES OF A CLASS OF PERSONS SIMILARLY SITUATED,
PLAINTIFFS-APPELLEES

v.

DONNA E. SHALALA, SECRETARY, HEALTH AND HUMAN SERVICES, DEFENDANT-APPELLANT

v.

JOSEPHINE BALISTRERI; FRED S. SCHERZ; KEVIN A. DRISCOLL; MINA AMES; EDMUNDO B. CARDENAS; ARLINE T. DONOHO; PATRICIA SLOAN; BETH ROBLEY; GOLDIE M. POWELL; RICHARD BAXTER,
PLAINTIFFS-INTERVENORS

Appeal from the United States District Court for the District of Arizona

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[Argued and Submitted: Jan. 13, 1998
Decided: Aug. 12, 1998]

Before: CHOY, SCHROEDER, and WIGGINS, Circuit Judges.

WIGGINS, Circuit Judge:

Medicare beneficiaries enrolled in health maintenance organizations ("HMOs") in Arizona sued the Secretary of Health and Human Services ("Secretary"). Their suit alleged a failure to enforce due process requirements and a failure to monitor HMO denials of medical services to enrolled Medicare beneficiaries. The district court granted Plaintiffs summary judgment, holding that HMO denials of medical services to Medicare beneficiaries constitute state action and that the regulations issued by the Secretary fail to provide due process. The district court issued an injunction mandating certain procedural protections for Medicare beneficiaries enrolled in HMOs. The Secretary appeals. We affirm.

I. Background

Congress passed the Medicare Act, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.*, in 1965 to provide a federal health insurance program for the elderly and the disabled. Today, a Medicare beneficiary can receive Medicare services in two different ways. The first is to receive Medicare on a fee-for-service basis. Under this option, the beneficiary goes to a health care provider for the necessary covered services; either the provider or the beneficiary will be reimbursed by the government for the cost of the services. The second, newer option is to enroll in an

HMO or other eligible organization.[1] *See* 42 U.S.C. § 1395mm(b).

In 1982, Congress authorized the Secretary to enter into "risk-sharing" contracts with HMOs. *See* § 1395mm. Under these contracts, HMOs provide to enrolled Medicare beneficiaries all the Medicare services provided in the statute, *see* § 1395mm(c)(2)(A), in exchange for a monthly flat payment from the Secretary, *see* § 1395mm(a).

The Medicare statute establishes in § 1395mm(c) procedural protections for those beneficiaries that enroll in HMOs. Among these, the HMO must "provide meaningful procedures for hearing and resolving grievances between the organization . . . and members enrolled . . . ." § 1395mm(c)(5)(A). HMO members must also have certain appeal rights:

> A member enrolled with an eligible organization under this section who is dissatisfied by reason of his failure to receive any health service to which he believes he is entitled and at no greater charge than he believes he is required to pay is entitled, if the amount in controversy is $100 or more, to a hearing before the Secretary to the same extent as is provided in [42 U.S.C. § 405(b)], and in any such hearing the Secretary shall make the eligible organization a party. If the amount in controversy is $1,000 or more, the individual or eligible organization shall, upon notifying the other party, be entitled to judicial review of the Secretary's final decision as provided in [42 U.S.C. § 405(g)]. . . .

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[1] Here, "HMOs" refers to all eligible health services providers, including HMOs and other "competitive medical plans." 42 U.S.C. § 1395mm(b).

§ 1395mm(c)(5)(B).

The Secretary created additional appeal protections in subsequent regulations. *See* 42 C.F.R. §§ 417.600—417.638. Under § 417.604, each HMO must establish appeal procedures and ensure that beneficiaries receive written information about the appeal and grievance procedures. *See* § 417.604(a). If the HMO makes an "organization determination" (defined in § 417.606) adverse to the enrollee, "it must notify the enrollee of the determination within 60 days of receiving the enrollee's request for payment for services." § 417.608(a)(1). An example of an adverse organization determination is an HMO's decision that certain medical services are not covered by Medicare. The notice to the beneficiary must "[s]tate the specific reasons for the determination" and inform the enrollee of his or her "right to a reconsideration." § 417.608(b). Failure to provide timely notice is an adverse determination and may be appealed by the enrollee. *See* § 417.608(c).

If the enrollee is dissatisfied with an adverse determination, a request for reconsideration may be filed within 60 days from the date of the notice. *See* §§ 417.614 & 417.616(b). Within 60 days of the request, the HMO may make a decision fully favorable to the enrollee. *See* § 417.620(a). If it decides to make a decision that partially or completely affirms the adverse determination, it must explain its decision in writing and forward the case to the Health Care Financing Administration ("HCFA"). *See* § 417.620(b). If the enrollee is dissatisfied with the result of the reconsideration, and the amount remaining in controversy is $100 or more, the enrollee has a right to a hearing before an administrative law judge ("ALJ"). *See* § 417.630. The enrollee can appeal that hearing decision to the Appeals

Council and then to the district court. *See* §§ 417.634 & 417.636.

The Secretary possesses a number of sanctions to ensure HMO compliance with the Medicare statute and the Secretary's regulations. First, the Secretary "may not enter into a contract . . . with an [HMO] unless it meets the requirements of [§ 1395mm(c)] and [§ 1395mm(e)]." 42 U.S.C. § 1395mm(c)(1). The specified sections require the HMO, inter alia, to provide all Medicare services to eligible enrollees, to have particular open enrollment periods, to provide enrollees annually with information on their rights, including appeal rights, to provide covered services "with reasonable promptness," to provide the aforementioned procedural protections, and not to exceed certain limits on rates charged to beneficiaries and the Secretary. §§ 1395mm(c) & 1395mm(e).

Second, the Secretary may terminate any contract with an HMO if she determines that the HMO has not met the terms of the contract or has not satisfied the statutory or regulatory requirements. *See* § 1395mm(i)(1). If the Secretary determines that an HMO has failed to provide necessary covered services to an enrollee and that failure has adversely affected the individual, the Secretary may seek civil money penalties, suspend enrollment, or suspend payment to the HMO. *See* § 1395mm(i)(6).

In 1993, five Medicare beneficiaries enrolled in an Arizona HMO sued the Secretary. Among other claims, Plaintiffs alleged that the Secretary "has failed and refused to take effective action to implement beneficiaries' notice and appeal rights when they are denied health care services by their HMOs," and "has failed and refused to provide Medicare beneficiaries enrolled

in HMOs with a procedure of obtaining review of HMO denial decisions contemporaneously with the denial decisions." In a decision not on appeal, the district court certified a nationwide plaintiff class.

In October 1996, the district court granted partial summary judgment to Plaintiffs on the claims described above. *See Grijalva v. Shalala*, 946 F.Supp. 747 (D. Ariz. 1996). The court held that the "organization determinations" made by HMOs constitute state action, triggering constitutional due process requirements. *See id.* at 751-53. The court also held that the regulations promulgated by the Secretary regarding adverse determinations by HMOs fail to provide sufficient due process to enrollees under *Mathews v. Eldridge*, 424 U.S. 319, 96 S.Ct. 893, 47 L.Ed.2d 18 (1976). *See Grijalva*, 946 F.Supp. at 756-60. In particular, the district court found that the notices issued by HMOs failed to provide adequate notice: they were often illegible, failed to specify the reason for the denial, and failed to inform the beneficiary that he or she had the right to present additional evidence to the HMO. *See id.* at 757-59. Therefore, "[s]ubsequent due process, available in the administrative review phase of the appeal, comes too late in many cases. . . ." *Id.* at 759. The district court also found that the language of § 1395mm(c)(1) ("The Secretary may not enter into a contract . . . with an eligible organization unless it meets the requirements of this subsection") was mandatory, requiring the Secretary to enforce her regulations by refusing to renew a contract with an HMO if the denial notices of that HMO fail to provide due process. *See id.* at 760.

The district court found that the Secretary violated § 1395mm(c)(1) by entering into a contract with any HMO that failed to provide timely notice for any and all

denials of service. The court held that the notice must be legible (at least 12-point type), state clearly the reason for the denial, inform the enrollee of all appeal rights, explain hearing rights and procedures, and provide "instruction on how to obtain supporting evidence, including medical records and supporting affidavits from the attending physician." *Id.* at 760-61. The district court also held that any hearing must be "informal, in-person communication with the decision-maker," available upon request for all service denials, and timely. *Id.* at 761. The district court also required expedited hearings for "acute care service denials." *Id.*

On March 3, 1997, the district court issued an injunction mandating the above requirements. *See Grijalva v. Shalala*, No. CIV 93-711 TUC ACM, 1997 WL 155392 (D. Ariz. Mar. 3, 1997).

The Secretary appealed the district court's decision in May 1997. The district court granted her a stay of its injunction pending this appeal.

II. Standards of Review

We review a grant of summary judgment de novo. *See Bagdadi v. Nazar*, 84 F.3d 1194, 1197 (9th Cir. 1996). We must determine, viewing the evidence in the light most favorable to the nonmoving party, whether there are any genuine issues of material fact and whether the district court applied correctly the relevant substantive law. *See id.* We may affirm on any ground supported by the record. *See Intel Corp. v. Hartford Accident & Indem. Co.*, 952 F.2d 1551, 1556 (9th Cir. 1991).

We review the scope of an injunction for an abuse of discretion or application of erroneous legal principles.

See SEC v. Interlink Data Network, 77 F.3d 1201, 1204 (9th Cir. 1996).

III. Discussion

A. *State Action Doctrine*

The Secretary appeals the district court's holding that HMO denials of medical services to enrolled Medicare beneficiaries constitute state action and therefore invoke constitutional due process protections.[2]

The actions of private parties are not subject to the requirements of constitutional due process unless they can fairly be considered government action. *See Shelley v. Kraemer*, 334 U.S. 1, 13, 68 S.Ct. 836, 92 L.Ed. 1161 (1948). We use the same standards to attribute the actions of private actors to the federal government under the Fifth Amendment as we do to attribute private actions to state governments under the Fourteenth Amendment. *See Kitchens v. Bowen*, 825 F.2d 1337, 1340 (9th Cir.1987).

The actions of private entities constitute state action under particular circumstances. In order to show that a private action is in fact state action, the plaintiff must show that "'there is a sufficiently close nexus between the State and the challenged action of the regulated entity so that the action of the latter may be fairly treated as that of the State itself.'" *Blum v. Yaretsky*, 457 U.S. 991, 1004, 102 S.Ct. 2777, 73 L.Ed.2d 534 (1982) (quoting *Jackson v. Metropolitan Edison Co.*, 419 U.S. 345, 351, 95 S.Ct. 449, 42 L.Ed.2d 477 (1974)). The government's regulation of the private actor is insufficient

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[2] The district court held that such HMO denials constitute "state action." We interpret this as holding that such HMO actions constitute government action, specifically federal action.

alone to show federal action. *See Blum*, 457 U.S. at 1004, 102 S.Ct. 2777; *Jackson*, 419 U.S. at 350, 95 S.Ct. 449. Government action exists if there is a symbiotic relationship with a high degree of interdependence between the private and public parties such that they are "joint participant[s] in the challenged activity." *See Burton v. Wilmington Parking Auth.*, 365 U.S. 715, 725, 81 S.Ct. 856, 6 L.Ed.2d 45 (1961). Government action exists if the challenged private action occurs under government compulsion. *See Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 170-71, 90 S.Ct. 1598, 26 L.Ed.2d 142 (1970). The government must do more, however, than merely acquiesce in the challenged action. *See Flagg Bros., Inc. v. Brooks*, 436 U.S. 149, 164, 98 S.Ct. 1729, 56 L.Ed.2d 185 (1978) (holding that government inaction is insufficient for state action). A detailed inquiry into the facts of the particular case may be necessary to determine whether there is state or federal action. *See Jackson*, 419 U.S. at 351, 95 S.Ct. 449.

In this case, the question is whether the challenged action—HMO denials of services to Medicare beneficiaries with inadequate notice—may fairly be treated as that of the federal government. We agree with the district court's cogent analysis and conclusion that, in the circumstances of the Secretary's regulation of and delegation of Medicare coverage decisions to HMOs, HMO denials of services to Medicare beneficiaries with inadequate notice constitute federal action.

We find that HMOs and the federal government are essentially engaged as joint participants to provide Medicare services such that the actions of HMOs in denying medical services to Medicare beneficiaries and in failing to provide adequate notice may fairly be

attributed to the federal government. The Secretary extensively regulates the provision of Medicare services by HMOs. HMOs are required, by the Medicare statute and their contracts with the Secretary, to comply with all federal laws and regulations. The Secretary is required to ensure, inter alia, that HMOs provide adequate notice and meaningful appeal procedures to beneficiaries. The Secretary pays HMOs for each enrolled Medicare beneficiary (regardless of the services provided). The federal government has created the legal framework—the standards and enforcement mechanisms—within which HMOs make adverse determinations, issue notices, and guarantee appeal rights. Medicare beneficiaries enrolled in HMOs may appeal an HMO's adverse determination to the Secretary, who has the power to overturn the HMO's decision. Each of these factors alone might not be sufficient to establish federal action. Together they show federal action. *See Catanzano v. Dowling*, 60 F.3d 113, 117-120 (2d Cir. 1995) (similar analysis in Medicaid context); *J.K. v. Dillenberg*, 836 F. Supp. 694, 697-99 (D. Ariz. 1993) (same).

The Secretary argues that the Supreme Court case of *Blum v. Yaretsky*, 457 U.S. 991, 102 S.Ct. 2777, 73 L.Ed.2d 534 (1982), mandates a finding that HMO adverse determinations are not state action. We disagree.

In *Blum*, the Supreme Court held that nursing home decisions made by doctors and administrators to transfer patients to other facilities, thereby terminating their Medicaid benefits, did not constitute state action. The Court held that the decisions at issue in the case turned "on medical judgment made by private parties according to professional standards that are not established by the State." 457 U.S. at 1008, 102 S.Ct.

2777. Because state officials did not have the power to approve or disapprove the nursing home decisions, but just altered the level of Medicaid benefits accordingly, the Court held that the decisions were not state action. *See id.* at 1010, 102 S.Ct. 2777.

Unlike the nursing home doctors and administrators in *Blum*, the HMOs in this case are not making decisions to which the government merely responds. HMOs are following congressional and regulatory orders and are making decisions as a governmental proxy—they are deciding that Medicare does not cover certain medical services. In *Blum*, by contrast, the nursing homes decided that certain medical services were no longer medically necessary. While such an inquiry may occur in HMO service denials, the decisions in the case at hand are more accurately described as coverage decisions—interpretations of the Medicare statute—rather than merely medical judgments (particularly when no reason for the denial is given other than that the service does not meet "Medicare guidelines . . . based upon [the HMO's] understanding and interpretation of Medicare . . . coverage policies and guidelines," to quote a typical notice provided by Plai[illegible]).

The district court's reasoning and holding that HMO service denials are federal action therefore do not run counter to *Blum*. As noted by the district court, the government cannot avoid the due process requirements of the Constitution merely by delegating its duty to determine Medicare coverage to private entities. *See* 946 F. Supp. at 752; *see also Burton*, 365 U.S. at 725, 81 S.Ct. 856 ("But no State may effectively abdicate its responsibilities by either ignoring them or by merely

failing to discharge them whatever the motive may be.").

We hold, therefore, that, when denying medical services to enrolled Medicare beneficiaries, HMOs are federal actors.

B. *Due Process and Mathews v. Eldridge*

The parties agree that the balancing test used by the Supreme Court in *Mathews v. Eldridge*, 424 U.S. 319, 96 S.Ct. 893, 47 L.Ed.2d 18 (1976), applies to determine the necessary procedural protections to ensure that due process is provided to Medicare beneficiaries enrolled in HMOs.

In *Mathews v. Eldridge*, the Supreme Court considered the sufficiency of the procedures by which Social Security disability benefits were terminated. *See* 424 U.S. 319, 96 S.Ct. 893, 47 L.Ed.2d 18 (1976). The Supreme Court held that constitutional due process is flexible, demanding particular protections depending on the situation. *See id.* at 334, 96 S.Ct. 893. The requirements of due process in a particular situation depend on an analysis of three factors:

> First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the functions involved and the fiscal and administrative burdens that the additional or substitute procedural requirements would entail.

Id. at 335, 96 S.Ct. 893. A court must balance these factors to determine whether the particular additional

procedural safeguards sought by a plaintiff are required in a given situation.[3] *See id.*

We agree with the district court's analysis of the *Eldridge* factors and its conclusion that due process requires additional protections for Medicare beneficiaries enrolled in HMOs.

1. *Private Interest at Stake*

The district court held that the private interest at stake from an HMO's initial denial of Medicare coverage is the potential that medical care will be precluded altogether. The court held that this interest is a substantial private interest in additional protections such as timely and effective notice of service denials. We agree.

In *Eldridge*, the Court held that the private interest at stake was the individual's interest in "uninterrupted receipt" of disability benefits. 424 U.S. at 340, 96 S.Ct. 893. The Court held that this interest was not based on financial need (unlike the situation of the welfare recipient in *Goldberg v. Kelly*, 397 U.S. 254, 90 S.Ct. 1011, 25 L.Ed.2d 287 (1970)), and does not implicate a high degree of potential deprivation. *See id.* at 340-41, 96 S.Ct. 893.

The district court was correct in holding that Plaintiffs' interest in Medicare benefits is greater than the interest of the plaintiff in *Eldridge*. As the district court noted, "[u]nlike *Eldridge*, the deprivation suffered from an HMO denial to provide care cannot so

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[3] The Secretary argues that, in general, the Secretary's views on the appropriate level of procedural protections should be accorded "great deference." There is nothing in *Mathews v. Eldridge* or subsequent cases to suggest that such is necessary or advisable.

easily be remedied by retroactive recoupment of benefits." 946 F.Supp. at 757. An HMO's denial of coverage is an initial refusal to provide any medical services. The mere fact that the enrollee may be able to go elsewhere and pay for the services herself is of little comfort to an elderly, poor patient—particularly one who is ill and whose skilled nursing care has been terminated without a specific reason or description of how to appeal.

The Secretary argues that the district court erred by "adjudicating a complex procedural scheme as falling short of basic standards of fairness, *without* conducting the sort of detailed inquiry needed." For example, the Secretary argues, the district court should have distinguished between different types of medical services and their urgency when considering this first *Eldridge* factor, the magnitude of the private interest at stake. The Secretary also argues that the district court's finding that the interests of Medicare HMO enrollees are "especially" great because they may not receive immediate medical care is erroneous because some beneficiaries can seek those services elsewhere (and then seek reimbursement from the HMO) or disenroll from the HMO. The Secretary's arguments fail. Although, in some cases, the effect of service denial may be remedied easily after the fact, the potential for irreparable damage is surely great when it comes to denial of medical services (particularly denial without notice of any reason for the denial), unlike the suspension of disability benefits pending review as in *Eldridge*. In many, if not most, cases, the denial of coverage may result in total failure to receive the services.

The Secretary argues that the district court failed to recognize that the Medicare program is not need-based,

a fact which the Secretary argues mandates holding against additional procedural protections. The Secretary cites to *Eldridge* for this proposition. The Court in *Eldridge*, however, discussed the fact that the disability benefits were not need-based in order to distinguish the case from that in *Goldberg v. Kelly*, 397 U.S. 254, 90 S.Ct. 1011, 25 L.Ed.2d 287 (1970), where the Court had held that a hearing was necessary prior to the suspension of welfare benefits. The Court did not hold that a program has to be need-based in order for this factor to weigh in favor of additional protections.

Other courts have found on similar facts that a significant private interest is at stake that weighs in favor of additional protections. *See, e.g., Kraemer v. Heckler*, 737 F.2d 214, 222 (2d Cir. 1984) ("In applying the balancing test, the private interest at stake [in the termination of Medicare coverage] should be weighed more heavily than in *Eldridge* because of the astronomical nature of medical costs."); *Vorster v. Bowen*, 709 F. Supp. 934, 946 (C.D. Cal. 1989) ("The private interest, in this case, is the claimant's need to obtain reimbursement for medical bills that he or she has already paid. That interest is fairly great. Congress enacted the [Medicare] program because of the special coincidence of medical needs and financial problems of the elderly."). The interest of the HMO enrollees in medical services weighs in favor of additional procedural protections beyond that offered by the Secretary's original regulations.

2. *Risk of Erroneous Deprivation*

The district court also held that factor two weighed in favor of greater procedural protections for Medicare beneficiaries enrolled in HMOs. The court reviewed Plaintiffs' analysis of notice failures and conducted its

own review of the notices provided to Plaintiffs. The court held that the notices failed to provide adequate explanation for the denials. *See* 946 F.Supp. at 757-58. We agree. This failure creates a high risk of erroneous deprivation of medical care to Medicare beneficiaries. The appeal rights and other procedural protections available to Medicare beneficiaries are meaningless if the beneficiaries are unaware of the reason for service denial and therefore cannot argue against the denial. "Due process requires notice that gives an agency's reason for its action in sufficient detail that the affected party can prepare a responsive defense." *Barnes v. Healy*, 980 F.2d 572, 579 (9th Cir. 1992). Therefore, inadequate notice creates the risk of erroneous deprivation by undermining the appeal process.

The Secretary attacks the district court's analysis of this factor by arguing that the court simply identified an "arguable problem" faced by enrollees— inadequate notice—rather than address whether that problem actually results in deprivations. The Secretary argues that the district court "simply *assumed* that the perceived failures of notice resulted in fewer appeals, and that more appeals would diminish erroneous deprivations." The Secretary fails to recognize the real problem: Inadequate notice renders the existence of an appeal process meaningless. Moreover, the question established by *Eldridge* is not whether the inadequate notices actually resulted in erroneous deprivations, but whether the inadequate notices created an unjustifiably high risk of erroneous deprivation. Because due process has at its foundation the notion of adequate notice, the risk of erroneous deprivation caused by ineffective notices points towards the need for added procedural

protections for Medicare beneficiaries enrolled in HMOs.

3. *The Government's Interest*

The Secretary argues that the district court paid only cursory attention to this factor, dismissing the government's concerns. The Secretary argues that the procedures sought by plaintiffs would impose a large burden on HMOs, which would accordingly affect the benefits received by enrollees.

The district court did not engage in as detailed an analysis of this third factor as of the other two. A shorter analysis, however, does not mean the analysis is cursory or dismissive. The Secretary has failed to show that the added procedural protections soug. t by Plaintiffs would result in significant additional costs to the government. Unlike the plaintiff in *Eldridge*, Plaintiffs do not seek a hearing prior to every denial, which would greatly increase costs. Adequate notices do not impose a burden on HMOs that outweighs the beneficiaries' need for them. "[A] weighing of the *Mathews [v. Eldridge]* factors suggests that the administrative burden of providing an explanation for denying a [certain benefit] is minimal in light of the added potential for spotting erroneously withheld [benefits]." *Barnes v. Healy*, 980 F.2d 572, 579 (9th Cir. 1992). The Secretary fails to advance any convincing argument that an additional burden on the government outweighs the effects of the other factors such that additional procedural safeguards are not necessary.

Taken together, the *Eldridge* factors point to a need for additional procedural protections for Medicare beneficiaries enrolled in HMOs, in particular for adequate notice of service denials, including the specific reason

for the denial and an explanation of appeal rights, and expedited review for critical care denials. We therefore affirm the district court's holdings on *Eldridge*.

C. *The Scope of the Injunction*

The Secretary challenges the scope of the injunction issued by the district court.[4] The scope of an injunction is reviewed for an abuse of discretion or application of erroneous legal principles. *See SEC v. Interlink Data Network*, 77 F.3d 1201, 1204 (9th Cir. 1996). "When

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[4] In addition, the Secretary argues that the district court should not have issued any injunction, because the proper course, if the existing regulations were insufficient to provide due process, was to remand the case to the Secretary for her to produce new regulations comporting with due process. The cases cited by the Secretary, however, do not support this argument in the present case.

For example, in *Thompson v. United States Dep't of Labor*, 885 F.2d 551 (9th Cir.1989), this court remanded the case to the Secretary on very particular facts. The Secretary had entered into a settlement agreement with a whistleblower who had sued the Department. Despite prior discussions on the question, the agreement was silent on the question of whether the Secretary could dismiss the complaints with prejudice. The Secretary then dismissed the complaints with prejudice. This court held that the Secretary could not dismiss the complaints with prejudice and remanded the case for the Secretary to decide if it still wanted to enter into the settlement agreement. *See* 885 F.2d at 558.

This case is not analogous. The Secretary never had adjudicative jurisdiction over this case. The Secretary does not provide any case that states that this court must remand to her on the facts of this case. The issuance of an injunction was within the district court's equitable powers. *See Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312-13, 102 S.Ct. 1798, 72 L.Ed.2d 91 (1982) (holding that a district court possesses the equity jurisdiction to issue an injunction, provided that it has subject matter jurisdiction and that Congress has not mandated otherwise).

injunctive relief is sought against a state agency or official, such relief 'must be no broader than necessary to remedy the constitutional violation.'" *Barnes v. Healy*, 980 F.2d 572, 576 (9th Cir. 1992) (quoting *Toussaint v. McCarthy*, 801 F.2d 1080, 1086 (9th Cir. 1986)).

The Secretary argues vociferously that the injunction issued by the district court was widely and irrationally broad in scope. For example, the Secretary repeatedly ridicules the district court's requirement of 12-point type for all notices of service denials. The scope of the district court's injunction, however, is not either an abuse of discretion or the result of application of erroneous legal principles.

The district court required legible (which requires 12-point type for senior citizens) and clear notices that adequately explain to beneficiaries the reasons for the denial of services and inform them of their appeal rights. The court required any hearings to be informal and in-person. An abuse of discretion is not apparent in these requirements. Moreover, many of them are already required by the Medicare statute or the Secretary's regulations (which might make them redundant, but does not make them an abuse of discretion). The court also required the Secretary to monitor the behavior of HMOs. This requirement is not an abuse of discretion given that Congress implicitly required such in the Medicare statute by forbidding the Secretary from entering into contracts with HMOs that did not comply with the statute or the regulations and by providing the Secretary with the power to sanction the HMOs.

The Secretary argues that the district court abused its discretion by prohibiting the Secretary from entering into new contracts with HMOs that fail to provide

the procedural protections mandated by the court. The Secretary argues that Congress provided the Secretary with a wide range of enforcement mechanisms, and that the district court could not require the Secretary to use the harshest mechanism. This argument fails. The Medicare Act mandated that the Secretary "may not enter into a contract . . . with an [HMO] unless it meets the requirements of [§ 1395mm(c)] and [§ 1395mm(e)]." 42 U.S.C. § 1395mm(c)(1). Under its clear meaning, this provision is not permissive; to the contrary, it is mandatory. The district court did not err or abuse its discretion.

The Secretary notes that, since the district court's summary judgment and injunction in favor of Plaintiffs, she has promulgated new regulations providing additional procedural protections for Medicare beneficiaries enrolled in HMOs. She asks us to review and modify the district court's injunction accordingly. Finding it unnecessary to do so, we decline her invitation. The district court has continuing jurisdiction over the modification of the injunction. *See Transgo, Inc. v. Ajac Transmission Parts Corp.*, 768 F.2d 1001, 1030 (9th Cir. 1985) (declining to remand to district court with directions to modify injunction, noting that the party "may apply directly" to the district court for modification in light of post-trial events). The Secretary may move in the district court for a modification of its injunction.

IV. Conclusion

For the foregoing reasons, we AFFIRM the district court's summary judgment and injunction in favor of Plaintiffs.

AFFIRMED.

APPENDIX B

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 97-15877
D.C. No. CV-93-00711-ACM

GREGORIA GRIJALVA; CAROL KNOX; MARY LEA; BEATRICE BENNETT; AND MILDRED MORRELL, INDIVIDUALS AND REPRESENTATIVES OF A CLASS OF PERSONS SIMILARLY SITUATED, PLAINTIFFS-APPELLEES

v.

DONNA E. SHALALA, SECRETARY, HEALTH AND HUMAN SERVICES

v.

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JOSEPHINE BALISTRERI; FRED S. SCHERZ; KEVIN A. DRISCOLL; MINA AMES; EDMUNDO B. CARDENAS; ARLINE T. DONOHO; PATRICIA SLOAN; BETH ROBLEY; GOLDIE M. POWELL; RICHARD BAXTER, PLAINTIFFS-INTERVENORS

AMERICAN ASSOCIATION OF RETIRED PERSONS, ET AL., AMICUS

[Filed: Nov. 12, 1998]

ORDER

Before: WIGGINS, Circuit Judge:

The panel votes to deny the petition for rehearing. Judge Schroeder votes to reject the suggestion for rehearing en banc and Judges Choy and Wiggins so recommend.

The full court has been advised of the suggestion for rehearing en banc and no active judge has requested a vote on whether to rehear the matter en banc. Fed. R. App. P. 35.

The petition for rehearing is denied and the suggestion for rehearing en banc is rejected.

APPENDIX C

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Civ. No. 93-711 TUC ACM

GREGORIA GRIJALVA, CAROL KNOX; MAY LEA, BEATRICE BENNETT, AND MILDRED MORRELL, AS INDIVIDUALS AND REPRESENTATIVES OF A CLASS OF PERSONS SIMILARLY SITUATED, PLAINTIFFS

JOSEPHINE BALISTRERI, FRED S. SCHERZ, KEVIN A. DRISCOLL, MINA AMES; EDMUNDO B. CARDENAS, ARLINE T. DONOHO, PATRICIA SLOAN, BETH ROBLEY, GOLDIE M. POWELL AND RICHARD BAXTER, PLAINTIFFS-INTERVENERS

v.

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, DEFENDANT

[Filed: Oct. 17, 1996]

ORDER

MARQUEZ, Senior District Judge.

This action involves the Medicare program and its coverage of medical care dispensed by Health Main-

tenance Organizations (HMOs).[1] Plaintiffs seek declaratory and injunctive relief against the Secretary for abdicating her responsibility to monitor HMOs and to ensure that HMOs provide Medicare covered benefits. Plaintiffs ask that the Court order Defendant Shalala, Secretary of Health and Human Services, to implement and enforce effective notice, hearing, and appeals procedures for HMO service denials. Plaintiffs and Defendant simultaneously move for summary judgment.

Defendant alleges that HMOs are privately owned entities and their actions cannot be imputed to the federal government. Defendant contends that this Court has no jurisdiction to review the Health Care Finance Administration's (HCFA's) supervision of HMOs. Defendant asserts that neither the Administrative Procedure Act (APA), Constitution, or the Medicare statutes provide for judicial oversight of the Secretary.[2] Defendant repeats her previous argument that, here, there can be no judicial review because

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[1] These plans include Competitive Medical Plans (CMPs) which provide more limited services than an HMO. Either type of plan can be a public or private entity. Both are risk-based, e.g. paid on a flat rate basis, rather than fee-for-service. Risk based organizations receive a predetermined per capita monthly prospective payment to cover Medicare beneficiaries. The organization is responsible for any difference between the prepaid capitated amount and the actual costs incurred to furnish medical services to its Medicare enrollees, hence the term "at risk."

[2] Defendants charge that Plaintiffs fail to specify the legal basis for their claims. The Court resolved this issue on December 15, 1994, when it denied Defendants' Motion to Dismiss. This Court waived the requirement of exhaustion under 42 U.S.C. § 405(g) and held that jurisdiction exists over this case pursuant to 42 U.S.C. § 1395mm. *See* Order filed December 15, 1994.

Plaintiffs failed to exhaust their administrative remedies.

Plaintiffs seek summary judgment for Defendant's failure to enforce service requirements on HMOs in violation of statutory mandates and the Due Process Clause of the Constitution. Plaintiffs complain HMOs either fail to provide any notice or provide inadequate notice when medical services are denied. Plaintiffs contend that the Constitution requires an expedited hearing before an HMO can deny services and that HMOs carry the burden of proof for Medicare denials.

A. Jurisdiction Revisited: 42 U.S.C. § 405(g)

Section 405(g) of the Social Security Act applies to service denials by HMOs because 42 U.S.C. § 1395mm provides:

> (B) A member enrolled with an eligible organization under this section who is dissatisfied by reason of his failure to receive any health service to which he believes he is entitled and at no greater charge than he believes he is required to pay is entitled, if the amount in controversy is $100 or more, to a hearing before the Secretary to the same extent as is provided in section 405(b) of this title, and in any such hearing the Secretary shall make the eligible organization a party. If the amount in controversy is $1000 or more, the individual or eligible organization shall, upon notifying the other party, *be entitled to judicial review of the Secretary's final decision as provided in section 405(g) of this title*, and both the individual and the eligible

> organization shall be entitled to be parties to that judicial review. (emphasis added).

42 U.S.C. § 405(b) requires that the Secretary make findings of fact, and decide the rights of any individual applying for a payment under this subchapter. Any decision by the Secretary which is in whole or in part unfavorable to a claimant "shall contain a statement of the case, in understandable language, setting forth a discussion of the evidence, and stating the Secretary's determination and the reason or reasons upon which it is based." 42 U.S.C. § 405(b). Further:

> Upon request . . . and showing in writing that rights may be prejudiced by any decision the Secretary has rendered, [the Secretary] . . . shall give . . . reasonable notice and opportunity for hearing. If a hearing is held, [the Secretary] shall, on the basis of evidence adduced at the hearing, affirm, modify, or reverse his findings of fact and such decision. Any such request . . . must be filed within sixty days after notice of such decision is received. . . .

Id.

42 U.S.C. § 405(g) provides for judicial review of a final decision by the Secretary. "A final judgment in the context of § 405(g) and § 1395mm(c)(5)(B) consists of two elements: (1) the presentment of a claim to the Secretary; and 2) exhaustion of administrative remedies. *Johnson v. Shalala*, 2 F.3d 918, 921 (9th Cir. 1993)." (Order filed December 5, 1994 at 4.) The presentment requirement, the non-waiveable criteria for jurisdiction, is not an issue here, *Id.* at 5; all Plaintiffs in

the instant case filed claims for Medicare covered services and protested HMO denials. (Plaintiffs' Supplement to Plaintiffs' Memorandum in Support of Motion for Certification of Class Action filed June 26, 1995.) This Court waived the exhaustion requirement by its Order of December 15, 1994, (*See* Order at 5-8); this Court previously held, and again affirms, that jurisdiction exists under § 405(g).

Abundant case law supports such jurisdiction under § 405(g) for challenges involving various Social Security entitlement Programs. *See e.g.*: *Johnson v. Shalala*, 2 F.3d 918 (9th Cir.1993) (exhaustion waived: Social Security Income (SSI) recipient challenged Social Security Administration policy of counting all in-kind loans as income); *Briggs v. Sullivan*, 886 F.2d 1132 (9th Cir. 1989) (exhaustion waived: challenge to Secretary's policy of withholding SSI beneficiaries' representative payments during time beneficiary was without representation; declaratory and injunctive action against Secretary for improper policy and procedure); *Schoolcraft v. Sullivan*, 971 F.2d 81 (8th Cir.1992) (exhaustion waived: Social Security disability beneficiaries challenged Secretary's failure to ensure that uniform standards were applied at all levels of review, specifically initial determination conducted by state agency), *cert. denied*, 510 U.S. 1081, 114 S. Ct. 902, 127 L.Ed.2d 93 (1994); *Himmler v. Califano*, 611 F.2d 137 (6th Cir. 1979) (exhaustion waived: applicants for Medicare benefits alleged due process violations when benefits were terminated by fiscal intermediary without notice and hearing); *Kraemer v. Heckler*, 737 F.2d 214 (2nd Cir. 1984) (exhaustion waived: due process challenge to Secretary's policy of allowing Utilization Review Committee (URC) to terminate Medicare without notice or

hearing); *Goodnight v. Shalala*, 837 F. Supp. 1564 (Utah 1993) (exhaustion waived: claim against state agency for procedural irregularities violating Medicare regulations and against Secretary for failure to enforce); *Vorster v. Bowen*, 709 F. Supp. 934 (C.D. Cal. 1989) (exhaustion waived: due process challenge to initial determination of coverage by private carrier providing Part B, Medicare supplemental insurance); *Fox v. Bowen*, 656 F. Supp. 1236 (D.Conn.1987) (exhaustion waived: fiscal intermediaries' routine denials of Medicare coverage, based on improper presumptions, for certain categories of physical therapy violated due process).

Assuming this Court correctly waived the exhaustion requirement for jurisdiction under § 405(g), there is nothing unique about 42 U.S.C. § 1395mm and its provisions for judicial review via § 405(g) of the Social Security Act which affects jurisdiction over claims against the Secretary just because dispensation of medical care is via an HMO.

B. State Action: HMO Service Denials

Defendant makes much of the fact that HMOs are private, non-governmental entities because it is a fundamental rule of law that due process under the Fourteenth Amendment attaches only to actions which may fairly be said to be those of the state. *Shelley v. Kraemer*, 334 U.S. 1, 13, 68 S. Ct. 836, 842, 92 L.Ed. 1161 (1948). Therefore, Plaintiffs' claim hinges on whether HMO denials of service constitute state action.

Defendant argues that HMOs are merely private providers who contract with the government to provide medical care to Medicare beneficiaries. Defendant's

scenario fits within the protected confines of *Blum v. Yaretsky*, 457 U.S. 991, 102 S. Ct. 2777, 73 L.Ed.2d 534 (1982). In *Blum*, the Supreme Court found nursing home decisions to transfer patients to lower care facilities did not constitute state action even though the transfer decision resulted in a corresponding termination of benefits. The transfer decisions, made by attending physicians and home administrators,[3] were made by private parties according to professional standards. *Id.* at 1008, 102 S. Ct. at 2787-88. Since there was no evidence that the State had exercised coercive power or provided significant encouragement, overt or covert, there could be no finding in law of state action. *Id.* at 1004, 102 S. Ct. at 2785-86.

Defendant, the State of Arizona, made this same argument in *J.K. v. Dillenberg*, 836 F. Supp. 694 (Ariz. 1993): "REBHAs [regional behavioral health authorities] are responsible for the decision making that Plaintiffs seek to enjoin, but [ ] they function as private entities whose actions cannot be attributed to the state." *Dillenberg*, 836 F. Supp. at 697. Judge John M. Roll distinguished the nursing homes in *Blum* as private providers which did not execute state responsibilities for a state created service, *Id.* at 698, from those in *Dillenberg*, where the state had delegated the entire responsibility for its mandated behavioral health care duties to REBAHs. The state action factors in *Dillenberg* were: 1) the private entities, REBHAs, were subject to extensive state involvement; and 2) the

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[3] URC transfers were not at issue in *Blum*, the issue having been settled prior to the Supreme Court's review of the case. *Blum* left open the issue of whether URC transfers constituted state action. *Kraemer v. Heckler*, 737 F.2d at 220.

contract required REBHAs to "'comply with all Federal, State, and local laws, rules, regulations, standards and executive orders, governing performance of duties . . . and shall comply with provisions of federal laws and regulations governing the Title XIX Program. . . ." *Id.* at 698-99.[4]

Similarly, the Second Circuit recently found that decisions made by certified home health agencies (CCHAs), non-governmental private entities, to deny or reduce the amount of home health care prescribed for Medicaid recipients are "state actions" that trigger due process rights to a fair hearing. *Catanzano v. Dowling*, 60 F.3d 113 (2nd Cir.1995). The Second Circuit found that the state defendants exercised significant control over the CCHAs: 1) the government paid for covered services; and 2) the government regulated CCHAs activities, issued directives which could not be ignored and created the legal framework which gov-

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[4] Following *Dillenberg*, Judge Richard M. Bilby ruled in *Perry v. Chen*, CIV 95-140 TUC RMB, 1996 WL 159808, that there was state action when HMO, AHCCCS health plans terminated authorization for previously covered Medicaid services. Judge Bilby reasoned the Due Process Clause of the Constitution requires notice and an opportunity for a face-to-face hearing because: 1) the HMOs are paid by AHCCCS for covered services; 2) the HMOs' activities are regulated by AHCCCS; 3) AHCCCS issues directives which plans must follow and creates through rules, contracts and policies the framework under which the plans act to dispense medical care to AHCCCS beneficiaries; 4) the challenged HMO decisions are based on medical judgment and cost effectiveness; and 5) appeal of HMO decisions are made to AHCCCS which has the ultimate power to correct erroneous denials. Judge Bilby concluded that the HMOs assumed obligations of the state to provide Arizona's version of Medicaid (AHCCCS) benefits to the needy.

erned the grievous activities. The Circuit found Judge Roll's reasoning in *Dillenberg* persuasive:

> "It is patently unreasonable to presume that Congress would permit a state to disclaim federal responsibilities by contracting away its obligations to a private entity."

Id. at 118 (quoting *Dillenberg*, 836 F. Supp. at 699).

It seems equally unreasonable that Congress would permit the Secretary to disclaim her responsibility to "determine whether individual is entitled to benefits under part A or part B of [Medicare], and [to determine] the amount of benefits under part A or part B of [Medicare]." 42 U.S.C. § 1395ff; *see also*, 42 U.S.C. § 405(b) (Secretary shall make findings of fact, and decide the rights of any individual applying for a payment under Medicare).

Other criteria of *Dillenberg* and *Catanzano* for finding state action apply as well: 1) the government pays for covered services; 2) the government regulates HMOs' activities as they apply to Medicare beneficiaries, especially benefit coverage determinations; 3) the Secretary issues regulations and directives which cannot be ignored; the Secretary creates the legal framework which governs the activities complained of by Plaintiffs;[5] and 4) Medicare beneficiaries appeal

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[5] The Secretary has the power to inspect and audit the HMOs to determine quality of service and financial stability. 42 U.S.C. § 1395mm(i)(3). The Secretary can terminate HMO contracts, 42 U.S.C. § 1395mm(i)(3), or impose civil fines for noncompliance, 42 U.S.C. § 1395mm(i)(6)(B). *See also*: Section C of this Order setting out the regulatory provisions under which HMOs are required to

HMO service denials directly to the Secretary, who has the power to overturn the HMO decision.

Defendant's argument that HMOs are *Blum*-type private providers ignores the Medicare scheme.[6] In risk-based, managed care, the HMO performs two functions: direct provider of medical care and insurer. In the fee-for-service system, separate entities perform these functions: medical providers, i.e., doctors, and insurance companies, e.g. Blue Cross Blue Shield. This case questions the performance of the latter function by private provider HMOs.

There is really nothing new about a private, non-governmental entity being involved in the administrative arena of Medicare.

> The determination and review procedures for claims arising under the two parts of the Act [Parts A and B] are similar. *Both are administered primarily through non-governmental organizations,*[7] *usually insurance companies, pursuant to contracts with*

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operate, specifically the notice and appeal procedures which apply to Medicare service denials.

[6] Congress created the Medicare program in 1965 by enacting Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.* In 1972, Congress expanded Medicare to cover the permanently disabled and authorized the program to reimburse HMOs for services to Medicare beneficiaries. The Tax Equity and Fiscal Responsibility Act of 1982, § 114(a), weakened participation standards for HMOs and prompted widespread use of risk-based HMOs by Medicare.

[7] Under Part A of Medicare, the organizations are called "intermediaries." Under Part B, the organizations are called "carriers."

> *the Department.* (footnote omitted). Claims for payment or reimbursement are submitted to the carrier, which makes an initial determination as to the claim and sends a notice of its action together with any payment to the claimant. If the claimant is dissatisfied, a request for review may be made, (footnote omitted).

Gray Panthers v. Schweiker, 652 F.2d 146, 149 (D. C. Cir. 1980) (emphasis added). These fiscal intermediaries act as agents for the Secretary. *Kraemer v. Heckler*, 737 F.2d at 215 (citing 42 U.S.C. § 1395h); *Fox v. Bowen*, 656 F. Supp. at 1249 (Conn.1987); *see also*: *Himmler v. Califano*, 611 F.2d at 140 (fiscal intermediary is alter ego of Secretary for day-to-day administration of Medicare program); *Vorster v. Bowen*, 709 F. Supp. at 946-47 (denials issued by carrier treated like official action; court found due process required detailed notice of reasons for denial by carrier).

There is nothing unique about the performance of these same duties by HMOs which warrants a contrary finding here. Even if HMOs' performance of administrative duties is somehow distinguishable from those authorized by 42 U.S.C. § 1395h, the Court finds that HMO denials of Medicare services are properly held state action under the analysis set forth in *Dillenberg* and *Catanzano.*

C. *Procedural Due Process and HMO Determinations That There is No Medicare Coverage for a Requested Service*

Defendant has not referred this Court to, and this Court has not found, any provision in the Medicare

statutes or regulations pertaining to HMOs, to suggest that beneficiaries of Medicare who are denied services by HMOs are entitled to any less procedural due process than beneficiaries who are denied fee-for-service coverage. There is nothing in the Congressional record which suggests that Congress intended any less than full benefits and rights to apply when it embraced HMOs as Medicare providers.[8]

The Medicare statute, 42 U.S.C. § 1395mm(c)(2)(A), requires HMOs to provide the same range of services to plan enrollees as provided for Medicare beneficiaries generally.[9] HMOs are further required to:

> (A) make the services described in paragraph (2) (and such other health services as such individu-

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[8] Defendants argue that Medicare enrollees in HMOs exchanged Medicare appeal rights for expanded medical care. The Court rejects this notion. As well, the Court does not consider the ability to disenroll from the HMO and reenroll with a fee-for-service provider appropriate relief for disputed HMO service denials. Such freedom of choice might serve to resolve disputes between treating physicians, but it would be poor public policy to offer such relief for service denials based on Medicare coverage determinations. As Plaintiffs point out, this would allow HMOs to shift their risk back to Medicare. Essentially, Medicare (the tax payer) would pay twice: once as a flat rate to the HMO ostensibly to cover the service and again as a fee-for-service, after the beneficiary disenrolled from the HMO and obtained the service.

[9] Part A of Medicare provides: inpatient hospital services up to 150 days; post hospital extended care services up to 100 days. 42 U.S.C. § 1395d(a). Part B provides: home health care services; medical and other health services, such as physicians' services; outpatient physical therapy; certain health clinic services; outpatient rehabilitation facility services; and facility services furnished in connection with certain surgical procedures. 42 U.S.C. § 1395k(a)(2), (s), (x) (1992).

> als have contracted for) (i) available and accessible to each such individual within the area served by the organization, with reasonable promptness and in a manner which assures continuity, and (ii) when medically necessary, available and accessible twenty-four hours a day and seven days a week, and
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> (B) provide for reimbursement with respect to services which are described in subparagraph (A) and which are provided to such an individual other than through the organization, if (i) the services were medically necessary and immediately required because of an unforeseen illness, injury, or condition and (ii) it was not reasonable given the circumstances to obtain the services through the organization.

42 U.S.C. § 1395mm(c)(4). HMOs "must provide meaningful procedures for hearing and resolving grievances between the organization . . . and members enrolled with the organization under [the Medicare program]." 42 U.S.C. § 1395mm(c)(5)(A).

The regulatory scheme adopted by the Secretary to implement the statutory mandates of 42 U.S.C. § 1395mm[10] is very similar to that set out for initial fee-

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[10] An HMO must establish grievance and appeals procedures, 42 C.F.R. § 417.600(a)(2)(i), for Medicare enrollees dissatisfied because they do not receive health care services to which they believe they are entitled, at no greater cost than they believe they are required to pay. 42 C.F.R. § 417.600(a)(2)(ii). These enrollees have the right to an ALJ hearing if the amount in controversy is $100 or more, 42 C.F.R. § 417.600(a)(2)(ii)(A), or have the right to judicial review, if the amount exceeds $1000, 42 C.F.R. § 417.600(a)(2)(ii)(B). "For any claimant whose disagreement with

for-service coverage denials rendered by fiscal intermediaries or carriers. Reconsideration and appeal procedures for intermediary decisions on Part A claims are covered by 42 C.F.R. §§ 405.701-730; reconsideration and appeal for Part B claims are covered by 42 C.F.R. §§ 405.801-812. The two are essentially the same. *Gray Panthers*, 652 F.2d at 149, n. 6. Reconsideration procedures for HMO denials are set out in 42 C.F.R. §§ 417.600-694.

An HMO must establish and maintain appeal procedures for issues that involve organization determinations, 42 C.F.R. § 417.604(a)(1)(i):[11] 1) payment for emergency or urgently needed services; 2) any other health service furnished by a provider other than the HMO that the enrollee believes is covered under Medicare and should have been furnished by the HMO; and 3) HMO's refusal to provide services that the enrollee believes should be furnished by the HMO and enrollee has not received them outside the HMO. 42 C.F.R. § 417.606(a).[12] "Within 60 days of receiving the enrollee's request for payment for services,"[13] an HMO

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the [HMO] at this stage does not amount to more than $100, that is the end of the process, according to the Secretary's procedures. There is no further review, and there is at no time an opportunity to present one's case personally to the decisionmaker." *Gray Panthers*, 652 F.2d at 149 (assessing identical provisions pertaining to initial coverage denials rendered by Medicare carriers (42 C.F.R. §§ 405.720, 405.730, 405.815)).

[11] *Compare* 42 C.F.R. § 405.801.

[12] *Compare* 42 C.F.R. §§ 405.704, 405.803.

[13] Unlike the fee-for-service system which determines coverage after services are rendered, the HMO system generally entertains the question based on an enrollee's request for medical services, prior to rendering care. Emergency, urgent care, and

must give notice to an enrollee of any adverse organizational determination. 42 C.F.R. § 417.608(a).[14] The notice must state the specific reasons for the determination and inform the enrollee of his or her right to reconsideration. 42 C.F.R. § 417.608(b).[15] Failure to provide timely notice constitutes an adverse organizational determination and may be appealed. 42 C.F.R. § 417.608(c).

The organizational determination is final and binding unless reconsidered. 42 C.F.R. § 417.612.[16] An enrollee who is dissatisfied with an organization determination may file a written request for reconsideration within 60 days of the determination.[17] 42 C.F.R. § 417.614; 42 C.F.R. § 417.616(c).[18] "The HMO [ ] must provide the parties to the reconsideration reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing." 42 C.F.R. § 417.618.[19]

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out-of-area services are provided by the HMO upfront and the initial determination for these services comes after the fact like fee-for-service denials. Therefore, HCFA's HMO Manual requires that the initial determination notice issue when a member requests payment or services. (Joint Statement of Facts at p. 20, HMO Manual 2403.2)

[14] *Compare* 42 C.F.R. §§ 405.702, 405.803.

[15] *Compare* 42 C.F.R. §§ 405.702, 405.804.

[16] *Compare* 42 C.F.R. §§ 405.708, 405.804.

[17] The request for reconsideration may be filed with the HMO, any local SSA office; or railroad retirement beneficiaries may file with the RRB. 42 C.F.R. § 417.616(a).

[18] *Compare* 42 C.F.R. §§ 405.710, 405.711, 405.807 (Part B reconsideration has a 6 month filing limitation).

[19] *Compare* 42 C.F.R. §§ 405.715 (HCFA performs Part A reconsideration; there is no right to in person participation by the

"If the HMO [ ] can make a reconsidered determination that is completely favorable to the enrollee, the HMO issues the reconsideration determination." 42 C.F.R. § 417.620(a). The HMO must issue its favorable decision within "60 calendar days from the date of receipt of the request for reconsideration" or submit the file to HCFA. 42 C.F.R. § 417.620(c)-(f). If on reconsideration, the HMO partially or wholly affirms its denial, the HMO must prepare a written explanation and send the entire case to HCFA. HCFA makes the reconsidered determination. 42 C.F.R. § 417.620(b).[20] HCFA contracts with Network Design Group (NDG) to make the reconsidered determination within 30 days. (Joint Statement of Facts ¶ 13.)

Notice of the reconsideration determination must be mailed to the enrollee, and if issued by the HMO, a copy of the determination must be sent to HCFA. 42 C.F.R. § 417.624. The notice must state the reasons for the reconsidered determination and inform the party that if the claim is for $100 or more, he or she has a right to a hearing before an Administrative Law Judge (ALJ).[21] *Id.*[22] The notice must describe the procedures for obtaining a hearing. *Id.*[23] A reconsidered deter-

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beneficiary), 405.809 (carrier performs reconsideration, there is no right to in person participation).

[20] *See* n. 19.

[21] For Medicare Part A claims, under circumstances involving constitutional challenges, there is an expedited appeal process which bypasses ALJ and Appeal Council review. 42 C.F.R. § 405.718.

[22] *Compare* 42 C.F.R. §§ 405.716, 405.811 (Part B claims for $100 are entitled to a carrier hearing; thereafter, claims of $500 or more can be appealed to an ALJ).

[23] *Compare* 42 C.F.R. § 405.811.

mination is final and binding, 42 C.F.R. § 417.630,[24] unless a written request for a hearing is filed within 60 days of the date of notice of the reconsidered determination, 42 C.F.R. § 417.632.[25]

Any party to the ALJ hearing may request the Appeals Council to review the case. 42 C.F.R. § 417.634.[26] Judicial review of the Appeals Council decision may be had if the amount in controversy is $1,000 or more. 42 C.F.R. § 417.636.[27]

The Court finds that the Medicare statute,[28] the Secretary's regulations,[29] and the Due Process Clause of the Constitution, unequivocally provide that a Medicare beneficiary is entitled to notice and hearing when an HMO denies services based on coverage determinations.

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[24] *Compare* 42 C.F.R. §§ 405.717, 405.812.

[25] *Compare* 42 C.F.R. §§ 405.717, 405.722.

[26] *Compare* 42 C.F.R. §§ 405.724, 405.815.

[27] *Compare* 42 C.F.R. §§ 405.730, 405.815.

[28] HMOs "must provide meaningful procedures for hearing and resolving grievances between the organization . . . and members enrolled with the organization under [Medicare]." 42 U.S.C. § 1395mm(c)(5)(A).

[29] "Within 60 days of receiving a request for payment for services, an HMO must give notice to an enrollee of any adverse organization determination." 42 C.F.R. § 417.608(a). The notice must state the specific reasons for the determination and inform the enrollee of his or her right to reconsideration. 42 C.F.R. § 417.608(b). When reconsidering a claim, the HMO must provide the beneficiary a reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing. 42 C.F.R. § 417.618.

In *Gray Panthers*, the appellate court for the District of Columbia Circuit found that due process applies even to Medicare denials for claims of $100 or less and requires a "genuine opportunity" to be heard, even though the "full fair hearing" described in *Goldberg v. Kelly*, 397 U.S. 254, 90 S. Ct. 1011, 25 L.Ed.2d 287 (1970), was not necessary. *Gray Panthers*, 652 F.2d at 152 n. 15, 158-59. The court defined "hearing" as "any confrontation, oral or otherwise,[30] between an affected individual and an agency decisionmaker sufficient to allow the individual to present his case in a meaningful manner." *Id.* at 148 n. 3. The exact form of the hearing does not upset the core requirements of due process "—adequate notice of why the benefit is being denied and a genuine opportunity to explain why it should not be." *Id.* at 165.

In *Gray Panthers*, the court found oral hearings were required in part because of deficiencies in the notice provided to beneficiaries. The court reasoned that, at the oral hearings, beneficiaries could obtain clarification about the basis for denial and have a meaningful opportunity to respond. The court limited its opinion to the facts of the case and conjectured that alternative procedures such as better notice might alleviate some, perhaps all, due process deficiencies. *Id.* at 148 n. 4, 166.

Exactly what process is owed the Medicare beneficiary by the HMO is determined by a balancing test,

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[30] "Paper hearings" can, depending on the total context of the entire notice and hearing process, provide an adequate opportunity to explain one's case. *Gray Panthers*, 652 F.2d at 165 (citing *Basciano v. Herkimer*, 605 F.2d 605 (2nd Cir.1978), *cert. denied*, 442 U.S. 929, 99 S. Ct. 2858, 61 L.Ed.2d 296 (1979)).

first established in *Mathews v. Eldridge*, 424 U.S. 319, 334-35, 96 S. Ct. 893, 902-03, 47 L.Ed.2d 18 (1976): the private interest at stake; the risk of an erroneous deprivation; the probable value of additional or substitute procedural safeguards, and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.

D. The Mathews v. Eldridge Balancing Test

1. The Private Interest

In *Mathews v. Eldridge*, the Supreme Court held that an evidentiary hearing, as provided for in *Goldberg v. Kelly*,[31] was not required prior to an initial termination of disability benefits. *Eldridge*, 424 U.S. at 340-50, 96 S. Ct. at 905-10. The *Eldridge* Court distinguished the welfare benefits at stake in Goldberg, as an interest "'not present in the case of . . . virtually anyone else whose governmental entitlements are ended—[that is,] that termination of aid pending resolution of a controversy over eligibility may deprive an eligible recipient of the very means by which to live while he waits.'" *Eldridge*, 424 U.S. at 340, 96 S. Ct. at 905 (quoting *Goldberg*, 397 U.S. at 264, 90 S. Ct. at 1018). The *Eldridge* Court concluded, "Eligibility for disability

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[31] The pretermination due process rights of *Goldberg*, rejected by the Court in *Eldridge*, are: 1) timely and adequate notice of the reasons for termination; 2) an effective opportunity to defend a claim by confronting adverse witnesses and by presenting the case, including evidence, orally; 3) retained counsel, if desired; 4) an impartial decisionmaker; 5) a decision based on the law and evidence adduced at the hearing; and 6) a statement of reasons for the decision and the evidence relied on. *Goldberg*, 397 U.S. at 266-71, 90 S. Ct. at 1019-22.

benefits, in contrast, is not based upon financial need." *Id.*

The Court, nonetheless, recognized that the degree of distinction could be easily overstated because a disability recipient is by definition, "unable to engage in substantial gainful activity" and correspondingly will usually be in a precarious economic position. *Id.* at 342, 96 S. Ct. at 588-89. The Court, however, found that there was less reason than in *Goldberg* to require a full blown hearing because any temporary loss in disability benefits could possibly be offset by access to private financial resources or if not, other governmental, such as state, welfare subsidy programs could temporarily replace the lost disability benefit. *Id.*

Finally, the Court considered the "possible length of wrongful deprivation of benefits" as an important factor in assessing the impact on the private interest at stake. *Id.* at 341-42, 96 S. Ct. at 905-06. In *Eldridge*, the time between an initial determination of ineligibility for disability benefits and a final determination exceeded one year. *Id.* But then, wrongfully withheld benefits could be retroactively recovered. *See Eldridge*, 424 U.S. at 340, 96 S. Ct. at 905 (full retroactive relief confines the claimant's interest to the uninterrupted receipt of benefits).

The private interest at stake from an initial denial of Medicare coverage "should be weighed more heavily than in *Eldridge* because of the astronomical nature of medical costs." *Kraemer v. Heckler*, 737 F.2d 214, 222 (2nd Cir.1984). The Second Circuit assessed the time between an adverse Utilization Review Committee (URC) decision which triggered termination of benefits

and the agency's affirmation of the termination which triggered appeal rights and concluded that the approximately three-week period could financially cripple all but the very wealthy. The court held that because the potential for personal liability for medical costs would most likely cause a patient to discontinue receiving medical care, due process attaches to URC denial decisions. *Id.*

The *Kraemer* court distinguished the procedures available to the recipient facing termination of Medicare benefits by the URC and those available in *Eldridge*. In *Eldridge*, the plaintiff asked for an evidentiary hearing or oral presentation prior to the initial termination of disability benefits. The Secretary had already provided: notification of the tentative assessment and reasons for the denial, including a summary of the evidence; the beneficiary had access to all the information being considered by the agency and had an opportunity to make written submissions, with the assistance of a treating physician to rebut the agency's information and tentative conclusion. In *Kraemer*, no procedural process was afforded the beneficiary prior to URC termination of benefits. *See also*: *Vorster v. Bowen*, 709 F. Supp. at 946 (disproportionate number of Medicare recipients live near the poverty level; in combination with the astronomical cost of medical care, there is a substantial interest in obtaining reimbursement for medical bills already paid); *Fox v. Bowen*, 656 F. Supp. at 1249-50 (private interest in receiving Medicare coverage for physical therapy; due process attaches to coverage denials which terminate receipt of physical therapy). *But see Himmler v. Califano*, 611 F.2d at 146 (post-denial notice and hearing via administrative appeal sufficient due process because no sub-

stantial deprivation; medical services are already received so the only issue is ultimate financial liability).

Here, the Court finds that Plaintiffs have a greater interest in Medicare benefits than the disability benefits assessed in *Eldridge*, especially because they are HMO enrollees. The HMO's initial adverse coverage determination in many cases prevents receipt of medical care. Unlike *Eldridge*, the deprivation suffered from an HMO denial to provide care cannot so easily be remedied by retroactive recoupment of benefits. When Medicare services are denied, they are often foregone and, depending on the medical condition, final adjudication may come too late to rectify the situation, especially if the deprivation contributed to or resulted in unnecessary pain and suffering or death. (*See* Volume I Plaintiffs' Declarations: Exhibit A in Support of Motion for Summary Judgment.)[32]

The Court is aware that many HMO denials involve emergency or urgent care services which occur after delivery of service and address only whether the patient is the financially liable party. This was the issue in *Gray Panthers* and *Vorster v. Bowen*. The Court finds the reasoning in *Gray Panthers* and *Vorster* persuasive and finds that in all instances, Medicare beneficiaries have a substantial interest in receiving timely services or timely payment for care already received.

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[32] The Court shall not repeat the sad case histories of the Plaintiffs, but this exclusion in no way makes their stories any less heart breaking. The Court finds that in each Plaintiffs' case the denial of Medicare services worked a substantial and painful deprivation upon the beneficiary.

2. The Risk of an Erroneous Deprivation through the Procedures Used

In 1993 and 1994, the rate of appeals from fee-for-service denials were respectively, 27 and 31 times higher than appeals from HMO denials. (Joint Statement of Facts at ¶ 15.)[33] Defendant argues that this evinces the great job being performed by HMOs. The Court concludes otherwise.

Plaintiffs reviewed 570 HMO adverse notices and report:

1. *Readability*: 52% of the notices reviewed were illegible, based primarily on criteria of 12-point type as the recognized minimum print size for readability by elderly persons.
2. *Reason for Denial*: 74% of the notices provided vague, ambiguous, nonspecific reasons for denial.
3. *Personal Liability*: only 41% contained an explanation of personal liability resulting from care incurred subsequent to denial.

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[33] For purposes of Plaintiffs' Motion for Summary Judgment, the Court assumes timeliness at all stages of the appeal process. The record reflects rampant timeliness problems, but Defendants submit any time problems have been recently resolved and that HMOs and NDG are now complying with regulatory deadlines. (Joint Statement of Facts at ¶ 16.) The Court believes strict compliance is mandatory, especially in light of the severe hardship which can be worked by a Medicare service denial and the fact that there is no expedited appeal mechanism for acute medical care decisions. Hospital discharges are the only services subject to immediate appeal by Peer Review Organizations (PROs). 42 C.F.R. § 417.605.

4. *Appeal Rights*: vast majority of the notices provided information on appeal rights. Ninety-six percent of the notices included the time frame for appeal; 91% directed claimants on where or with whom to file the appeal; 73% explained that additional evidence could be provided; only 10% provided information about Peer Review Organization (PRO)[34] review.

(Volume III Plaintiffs' Exhibit C in Support of Motion for Summary Judgment at 2.)

The Court additionally reviewed the denial notices it found sprinkled throughout the 44 declarations of party Plaintiffs. (See Volume I Plaintiffs' Declarations Exhibit A in Support of Motion for Summary Judgment at 2, 9, 10, 13, 20, 23, 30, 33, 38, and 42.)[35] Of these ten examples, six were issued in 1995, two in 1994, one in 1993, and one in 1992. The Court found the notices failed to provide adequate reasons for the denials. Not one notice provided the specific basis for coverage denial; the notices only included explanations like, "beneficiary no longer receiving "skilled nursing care" and therefore, based on the HMO's "understanding of Medicare coverage policies," the HMO would not continue to provide the care after some date

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[34] PROs are independent organizations of health care professionals which by law HCFA must contract with to review the quality of care given to Medicare beneficiaries. (Joint Statement of Facts at ¶ 35); 42 U.S.C. § 1395mm(i)(1). Congress mandated funding for PRO review activities. 42 U.S.C. § 1395mm(i)(7)(B) and (C).

[35] The Court finds that these are not isolated cases. *See* same Exhibit at 11, 19, 27, 29, 35, 37, and 41 (supporting affidavits of various client advocacy groups).

certain—usually two days from the day the letter was written. This does not inform the beneficiary of the factual basis for the denial, nor enlighten him or her as to what specific service is not covered and why. Without proper notice, the claimant must guess at what evidence to submit for reconsideration of the claim. *Gray Panthers*, 652 F.2d at 168.

The notice format used by the HMOs hides the ball. For example, the notices reviewed by the Court were primarily denials for Skilled Nursing Facility (SNF) care and they all failed to include important coverage information:

> Coverage for care provided in a skilled nursing facility exists, if one of three criteria are met: 1) the patient requires skilled nursing services or skilled rehabilitation services, i.e., the care is being furnished by or under the supervision of professional or technical personnel; 2) the patient requires these skilled services on a daily basis; and 3) as a practical matter, considering economy and efficiency, the daily skilled services can be provided only on an inpatient basis in a Skilled Nursing Facility (SNF). The services must also be furnished pursuant to a physician's orders and be medically necessary.

Health Care Financing Administration Manual at § 3132.

A denial of coverage because a SNF is providing custodial, nonskilled, nursing care should identify which noncoverage factor(s) applies. Custodial care criteria is set forth in another section of the Health Care Financing Administration Manual, § 3159. Reference to

this section would also assist claimants in forming appeal arguments.

Without this type of notice, a claimant cannot begin to fathom what additional evidence to present to rebut the denial. *Gray Panthers*, 652 F.2d at 168; *Vorster v. Bowen*, 709 F. Supp. at 946-47. "Congress, in enacting and amending Medicare, has repeatedly recognized that the elderly, as a group, are less able than the general populace to deal effectively with legal notices and written registration requirements—. . . 'due to inattention or inability to manage their affairs.'" *Gray Panthers*, 652 F.2d at 169 (quoting S. Rep. No. 1230, 92d Cong., 2d Sess. 38 (1972)). "To countenance granting them less than adequate notice of the reasons for denial of medical benefits would be inconsistent with the Congressional intent, to say the least." *Id.* at 169.

In 25% of the notices reviewed by Plaintiffs, or in eight of the ten reviewed by the Court, the HMO failed to inform the claimant that he or she had a right to present additional evidence to the HMO for reconsideration. This omission violates 42 C.F.R. § 417.618. All the notices fail to direct claimants to their attending physicians as a primary means for obtaining substantiating evidence of medical necessity to rebut a denial. HMOs ignore that the managed care system has made strange bed-fellows of provider doctors who in the fee-for-service system provided patient advocacy for many claim denials. *See Kraemer*, 737 F.2d at 222 (URC only notifies physician to appear in advocacy of patient and there are "built-in" incentives for them not to). At best, HMO policies and procedures ignore the void; at worst, policies and procedures, such as "gag rule" contract provisions, eliminate this key evidentiary source.

Defendant argues that the HMO considers the claimant's medical records on reconsideration, but without additional evidence from the treating physician regarding medical necessity, HMO reconsideration approximates a "rubber stamp" of the initial denial. This has grave consequences because an HMO denial may mean the enrollee will go without medically necessary service. Given the length of time it takes for further appeal of the HMO denial, deprivations will certainly have significant impacts on quality of life and some may even be life threatening.

Due process requires a meaningful opportunity to present one's case at a meaningful time. *Gray Panthers*, 652 F.2d at 164. The statute and regulations reflect this standard. 42 U.S.C. § 1395mm(c)(4) requires that an "HMO must provide meaningful procedures for hearing and resolving grievances. . . ." 42 C.F.R. § 417.618 requires that an "HMO must provide parties to the reconsideration reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing." Some HMOs enact these provisions by allowing the request for reconsideration to be filed with the HMO in person. Even where the HMO informs a claimant that evidence can be provided in person, the notices fail to describe any procedures for securing an in-person communication with the HMO person reconsidering the claim. *See Gray Panthers*, 652 F.2d at 157 (a phone number on the notice doesn't mean the claimant has an opportunity to speak directly to the decisionmaker; value of informal hearing is the ability to talk directly to the decisionmaker). The Court is not aware of any HMO providing any type of in-person communications, such as informal hearings.

The statutes and regulations also provide for direct appeal of quality of service complaints to PROs. 42 U.S.C. § 1395mm(i)(7). The HMO must have an outreach program designed to apprise enrollees of the peer review system, its purpose, and the method for securing PRO review. 42 U.S.C. § 1320c-3(a)(4)(B). Quality of service includes under-utilization and continuity of care issues. *Id.* Both could arise within the context of a service denial. For this reason, notices should, but routinely do not, include any reference to the PRO appeal process.

The Court finds that existing reconsideration procedures followed by HMOs fail to secure minimum due process for Medicare beneficiaries. Notice and informal hearing requirements set forth by statute and regulations are all but ignored. The existing system fails to provide "a meaningful opportunity" to present the claim "at a meaningful time." Subsequent due process, available in the administrative review phase of the appeal, comes too late in many cases: assuming no delay by claimant, the HMO has 60 days to make the reconsideration decision; HCFA/NDG has 30 days to decide reconsiderations not granted by the HMO;[36] if the claim is for less than $100 there is no further due process; if the claim is for $100 or more, the matter can be appealed to an ALJ. In 1994, ALJ review took approximately 250 days. (Joint Statement of Facts at ¶ 17.) This Court, as did the court in *Gray Panthers*, concludes:

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[36] Settlement agreement in class action law suit, *Levy v. Sullivan*, No. 88-3271, 1989 WL 265476 (C.D.Cal. March 14, 1989); (Medicare & Medicaid Guide ¶ 37,809 at 19,748).

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> Current procedures allotted to the elderly Medicare claimant, probably disadvantaged by disability and poverty, resemble playing against a stacked deck— . . . [and result] in a significant possibility of deprivation.

Gray Panthers, 652 F.2d at 172.

3. The Government's Interest, Including the Fiscal and Administrative Burdens that the Additional or Substitute Procedural Requirements Would Entail

The alternative procedural safeguards discussed by this Court entail no greater fiscal and administrative burdens for Defendant than that contemplated by Congress and provided for by applicable law and regulation.[37] A more meaningful appeal process by the HMO may actually reduce fiscal burdens on the federal government because improper denials by HMOs cause Medicare beneficiaries to return to fee-for-service providers at greater expense to the government. In conclusion, the burden of proper notice and an opportunity to be heard on reconsideration by the HMO does not outweigh the substantial interest at stake and the risk of erroneous deprivation posed by the existing procedures.

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[37] The Court finds no statutory basis for Plaintiffs' proposal that appellate review place the burden of proof on the HMO and the HMO carries the burden on reconsideration before the NDG. (Joint Statement of Facts at ¶ 14.) Congress placed the burden on the claimant to establish eligibility, *Ward v. Schweiker*, 686 F.2d 762, 765 (9th Cir.1982), and this Court is not inclined to disrupt this chosen balance.

E. Relief: Judicial Authority to Order the Secretary of Health and Human Services to Enforce Regulatory and Statutory Provisions of 42 U.S.C. § 1395mm

1. Enforcement Decisions are Generally Committed to Agency Discretion

Defendant argues that there can be no judicial review of the Secretary's enforcement activities, or lack thereof.

> Review is not to be had if the statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion . . . —if no judicially manageable standards are available for judging how and when an agency should exercise its discretion, then it is impossible to evaluate agency action for "abuse of discretion."

Heckler v. Chaney, 470 U.S. 821, 830, 105 S. Ct. 1649, 1655, 84 L.Ed.2d 714 (1985). Under *Heckler v. Chaney*, refusal to take enforcement action by an administrative agency is presumptively nonreviewable. *Id.* (citing Administrative Procedure Act (APA); 5 U.S.C. § 701(a)(1) and (a)(2)). The presumption, however, can be overcome where the statute provides guidelines for the agency to follow for then there is law to apply. *Id.*

The statute discussed in *Chaney* was a general provision: "the Secretary is authorized to conduct examinations and investigations. . . ." *Id.* at 835, 105 S. Ct. at 1657. The Court described this language as permissive compared to language it had identified in *Dunlop v.*

Bachowski, 421 U.S. 560, 95 S. Ct. 1851, 44 L.Ed.2d 377 (1975), as mandatory: "the Secretary shall investigate such complaint and, if he finds probable cause to believe that a violation ... has occurred ... he shall ... bring a civil action. . . ." *Id.* at 833, 105 S. Ct. at 1657. In the latter, there is law to apply; in the former, a refusal to institute proceedings is a decision "committed to agency discretion by law." *Id.* at 834-35, 105 S. Ct. at 1657. (quoting APA § 701(a)(2)).

The statutory provisions at issue in this case are contained in 42 U.S.C. § 1395mm(c) which provides:

> (1) The Secretary *may not* enter into a contract under this section with an eligible organization unless it meets the requirements of this subsection ...

Subsections 4-6 address service and continuity of care standards, notice and hearing procedures, and appeal rights held by Medicare recipients. The Court finds that Congress expressly prohibits the Secretary from entering into arrangements with HMOs which fail to meet these requirements. *Cf. Barron v. Reich*, 13 F.3d 1370, 1375 (9th Cir.1994) ("shall" or "shall not" reflect mandatory duties; "may" describes a permissive function). As evident from the Court's analysis in the prior sections of this Order, the provisions and requirements of 42 U.S.C. § 1395mm(c) provide an ample basis in law to apply to the facts of this case.

The Court finds that the Secretary violates 42 U.S.C. § 1395mm(c)(1) by entering into a contract with any HMO that fails to meet the following notice requirements:

Notice:

1. Shall always be given for any and all denials of service;

2. Shall be timely;

3. Shall be readable: at least 12-point type;

4. Shall state the reason for denial clearly and in such terms as to enable the enrollee to argue his or her case;

5. Shall inform the enrollee of all appeal rights, including PRO review;

6. Shall inform the enrollee of the right to a hearing on reconsideration and that additional evidence may be presented, in person, and shall explain the procedure for securing an informal hearing, and

7. Shall provide instruction on how to obtain supporting evidence, including medical records and supporting affidavits from the attending physician. The HMO must abolish any policy or procedure which would impede such advocacy.

The Court finds that the Secretary violates 42 U.S.C. § 1395mm(c)(1) by entering into a contract with any HMO that fails to meet the following hearing requirements:

Hearing:

1. Shall be informal, in-person communication with the decisionmaker;

2. Shall be available upon request for all service denials, and

3. Shall be timely according to the seriousness of the medical condition implicated by the denied service:

Immediate hearing shall be available for acute care service denials, specifically where delivery of the service is prevented by the denial. (Assuming the HMO's reconsideration decision will be correspondingly expeditious, the appeal to NDG will be expedited for these cases). All other hearings can be within the normal course of the HMO's 60-day time frame for reconsideration, especially for more routine, nonacute medical care decisions or when care has been rendered and financial liability remains as the only issue.

2. Abuse of Discretion

An example of the Secretary's discretionary enforcement power appears in 42 U.S.C. § 1395mm(i)(1) which provides that she may terminate a contract prior to its expiration, upon finding that the HMO substantially fails to meet certain conditions, including those at issue here. Additionally, if she determines there is substantial noncompliance, she may impose civil monetary fines, suspend enrollment, or prevent an HMO from expanding its service area. 42 U.S.C. § 1395mm(i)(6).

Here, the Court reviews for abuse of discretion. *Heckler v. Chaney*, 470 U.S. at 833 n. 4, 105 S. Ct. at 1656 n. 4 (consciously and expressly adopted policy that is so extreme as to be an abdication of statutory responsibility is an abuse of discretion). Has the Secretary wholly abdicated her enforcement responsibilities? Is her policy of "continual improvement," so extreme as to undermine the fundamental statutory scheme that the Secretary be empowered to ensure that HMOs provide an effective and efficient medical delivery system to Medicare beneficiaries?

Plaintiffs urge the affirmative and proffer evidence that the Secretary fails to collect service utilization data; has a policy of encouraging voluntary improvement rather than penalizing HMOs; fails to use PROs to effectively review underservicing, and fails to implement a beneficiary complaint system. The Secretary admits to problems with the HMO delivery system, but counters that under her tutelage, the HMOs have continually improved and many of Plaintiffs' complaints have been corrected. The Court finds that there are material facts in dispute as to the effectiveness of the Secretary's monitoring and her enforcement choices. Summary judgment is not appropriate to determine whether she has abused her discretion.

Accordingly.

IT IS ORDERED that Defendant's Motion for Summary Judgment is DENIED.

IT IS FURTHER ORDERED that Plaintiffs' Motion for Summary Judgment is GRANTED in part and DENIED in part.

IT IS FURTHER ORDERED that within 20 days of the filing date of this Order the Plaintiff shall file a proposed form of judgment in accordance with the findings of this Court; Defendant shall respond.

IT IS FURTHER ORDERED that if the procedural changes resulting from this Order do not rectify delivery of care and quality of service issues, the Court retains jurisdiction over this case to reconsider the issue of the Secretary's discretionary enforcement duties and to refer the matter to a special master pursuant to Federal Rule of Civil Procedure 53.

APPENDIX D

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

No. CIV 93-711 TUC ACM

GREGORIA GRIJALVA; CAROL KNOX; MARY LEA; BEATRICE BENNETT; AND MILDRED MORRELL, AS INDIVIDUALS AND REPRESENTATIVES OF A CLASS OF PERSONS SIMILARLY SITUATED, PLAINTIFFS

JOSEPHINE BALISTRERI; FRED S. SCHERZ; KEVIN A. DRISCOLL; MINA AMES; EDMUNDO B. CARDENAS; ARLINE T. DONOHO; PATRICIA SLOAN; BETH ROBLEY; GOLDIE M. POWELL AND; RICHARD BAXTER, PLAINTIFFS-INTERVENERS

v.

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, DEFENDANT

[Filed: March 3, 1997]

JUDGMENT

On October 17, 1996, the Court entered an Order in this case, which denied the Defendant's Motion for Summary Judgment and granted in part and denied in part, Plaintiffs' Motion for Summary Judgment. In accordance with the findings and conclusions set out in that Order, the Court hereby issues judgment as follows:

IT IS ORDERED that Defendant Shalala require her Medicare contracting health maintenance organizations (HMOs)[1] to give their enrollees written notice whenever a coverage determination results in a service or referral requested by a health care provider, enrollee, or person acting on his or her behalf, being denied, or an ongoing course of treatment being reduced or terminated.

Denial notices shall meet the following minimal requirements:

(a) Notice shall be given promptly, but no more than five working days after written or oral request for a service or referral by a health care provider, enrollee, or person acting on his or her behalf, and at least one working day before reduction or termination of a course of treatment.[2]

(b) It may be delayed in exceptional circumstances for up to 60 days, if an HMO needs additional information to make a responsibly considered medical determination. To obtain an extension of the five-day notice requirement, the HMO must notify the enrollee that it needs additional information, specifically: what additional information it needs, the steps necessary to acquire the information, and the time estimated for completing the investigation.

(c) It shall be on a clear, readable form designed by the Defendant, in at least 12-point type, and include the following information:

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[1] All references in this document to HMOs shall include CMPs (comprehensive medical plans as defined in 42 U.S.C. § 1395(b)).

[2] Failure to provide timely notice constitutes an adverse determination and may be reconsidered. *See e.g.*, 42 C.F.R. § 417.608(c).

(i) an explanation in lay language of the coverage rule upon which the adverse decision was based, sufficiently detailed to allow the enrollee to understand the decision and argue his or her case;

(ii) a description of the regular and expedited appeal processes, and an explanation of the Peer Review Organization (PRO) complaint and quality review process;

(iii) a description of the additional evidence that would support the enrollee's position; instructions on how to obtain doctor's letters and medical records in support of the enrollee's position—which shall be freely provided by the HMO;[3] and how and when the enrollee may submit such evidence (in-person, if desired);

(iv) the procedures for securing an informal hearing before the decision-maker for reconsideration.

IT IS FURTHER ORDERED that the Secretary shall monitor and investigate the compliance of HMOs with the foregoing notice requirements. If the Secretary determines that a contracting HMO has failed to substantially comply with these notice requirements, the Secretary is prohibited from renewing or entering into a subsequent Medicare contract with the HMO.

IT IS FURTHER ORDERED that the Secretary shall provide Medicare HMO enrollees with an administrative reconsideration process for all adverse service decisions meets the following minimal requirements:

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[3] This does not mean that doctors are required to submit supporting letters if they believe the health service at issue is not warranted.

(a) First level reconsideration by the HMO shall include informal, in-person communication with the reconsideration decision-maker;[4]

(b) An expedited reconsideration process shall be made available when services are urgently needed, such as where acute care services are being denied or terminated: certain types of nursing facility care, certain types of home health and therapy services, and denials of certain types of non-cosmetic surgery.

An enrollee can establish that services are urgently needed by providing a written explanation of urgency from his or her doctor. Plan doctors shall be free to give supporting documentation without fear of retaliation or reprisal from the HMO.

A doctor's statement is not required to trigger expedited reconsideration. Under certain circumstances, especially where acute care services are being denied or terminated, lay testimony may suffice to establish that the care is urgently needed.

(c) An expedited decision by the HMO must be issued within three working days of the request for expedited reconsideration. Either the HMO or the enrollee may request up to ten additional working days to obtain evidence;

(d) Upon denial of an expedited reconsideration by the HMO, the independent HCFA review agency (currently NDG) shall complete review, as

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[4] The due process requirement of informal in-person hearings provides a great degree of flexibility and allows for creative approaches to address Defendant's logistic concerns. For example, informal hearings might be conducted telephonically, and beneficiaries in ill health could be represented by close friends or family members.

provided by law, within ten working days of the request for HCFA review;

(e) When acute care services are denied, so as to trigger the expedited reconsideration process, services must continue until a final reconsideration decision has been issued;[5]

(f) Any HMO policy or procedure that impedes an enrollee from obtaining supporting evidence, including medical records and letters from health care providers, is prohibited.

IT IS FURTHER ORDERED that the Secretary shall monitor and investigate the compliance of HMOs with the foregoing hearing requirements. If the Secretary establishes that a contracting HMO has failed to substantially comply with these hearing requirements, the Secretary is prohibited from renewing or entering into a subsequent Medicare contract with the HMO.

IT IS FURTHER ORDERED that the Secretary shall monitor and investigate the compliance of HMOs with the foregoing requirement that plan doctors be free to give supporting documentation without fear of retaliation or reprisal from the HMO. If the Secretary establishes that an HMO has retaliated in any way or manner against any doctor, the Secretary is prohibited from renewing or entering into a subsequent Medicare contract with the HMO.

IT IS FURTHER ORDERED that the Defendant shall implement the foregoing changes in the HMO notice

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[5] This does not prevent services from being terminated if the attending physician determines that continued treatment may be harmful to the enrollee.

and hearing procedures within 120 days of entry of Judgment.

IT IS FURTHER ORDERED that Count IV of Plaintiffs' Complaint is DISMISSED.

THE COURT FINDS that there are material issues of fact concerning the Defendant Secretary's compliance with the enforcement sections of the Medicare HMO statute that prevent the Court from entering summary judgment on Count I of the Complaint. These material issues of fact are set out in the parties' Joint Statement of Facts, at pages 11 to 25.

IT IS FURTHER ORDERED that the Court shall retain jurisdiction over this case for a period of three years from the date of implementation by Defendant to determine whether the procedural changes ordered above will rectify Count I delivery of care and quality of service issues. If the Plaintiffs believe that these issues have not been resolved, they may return to the Court at any time within the three-year period and request relief.

DATED this 3rd day of March, 1997.

/s/ ALFREDO C. MARQUEZ
ALFREDO C. MARQUEZ
Senior U. S. District Judge

APPENDIX E

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

No. CIV 93-711-TUC-ACM

GREGORIA GRIJALVA; CAROL KNOX; MARY LEA; BEATRICE BENNETT; AND MILDRED MORRELL, AS INDIVIDUALS AND REPRESENTATIVES OF A CLASS OF PERSONS SIMILARLY SITUATED, PLAINTIFFS

JOSEPHINE BALISTRERI; FRED S. SCHERZ; KEVIN A. DRISCOLL; MINA ARLINE T. DONOHO; PATRICIA SLOAN; BETH ROBLEY; GOLDIE M. POWELL; AND RICHARD BAXTER, INTERVENERS

v.

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, DEFENDANT

[Filed: June 11, 1997]

ORDER

On March 3, 1997, this Court ordered Defendant to implement certain notice and hearing procedures within 120 days. Defendant filed her Notice of Appeal on May 2, 1997. On May 12, 1997, Defendant filed a motion with this Court asking for a stay of the March 3, 1997 Order. Defendant contends that many of the required changes identified by this Court are currently being addressed by a proposed rule change to establish a new expedited

appeals process for Medicare beneficiaries enrolled in HMOs. "The April 30 regulations provide Medicare beneficiaries (including the Plaintiff class) with many of the procedural rights ordered by the Court, and, in some cases, actually hold HMOs to a more stringent standard than is required by the Court's Judgment." (Defendant's Motion for a Stay at 3.) The Court is also aware of other efforts on the part of state and federal legislatures which are addressing the same issues addressed by this Court in its March 3, 1997 Order. It is sincere hope of this Court that on appeal much of the March 3, 1997 Order might be moot because of these efforts.

The Court, however, finds fault with the Defendant's complaint that "several of the provisions of the Judgment are particularly problematic." (Defendant's Motion for Stay at 3.) Again, Defendant refers to: "such requirements in the Judgment as issuance of written notice of *all* (not just urgent) denials of care within five working days, provision of notice for all oral as well as written requests and the continuation of all 'acute care services' (vaguely defined) during reconsideration, would, if implemented on even a temporary basis, cause harm to HCFA, HMOs, and most importantly, the Medicare beneficiaries.'" (Defendant's Motion to Stay at 3-4 (citing 2d Fried Decl. ¶¶ 12-13.) Defendant made this same argument during the briefing on the form of Judgment. The Court presumed to clarify for Defendant the breadth of its ruling by emphasizing on page one of the Judgment that notice and hearing requirements apply "whenever a coverage determination results in a service or referral . . . being denied, or an ongoing course of treatment being reduced or terminated." (Judgment filed on March 3, 1997 at 1.) Plain-

tiffs never argued, nor has this Court ever suggested, that the notice and hearing rights identified by the Court attach during the doctor patient visit.[1] The notice and hearing requirements identified by this Court have always been discussed within the context of the HMO denying a service because it determines the service to be not covered by Medicare, not denials of service by doctors when they determine such care not to be medically necessary.

The Court made every attempt to confine its Judgment to what it deemed Constitutional parameters, and to resist mandating details which in this Court's opinion are better left to the Secretary and the medical profession. For example, the Court restrained its Judgment from defining "acute care services" when it ordered that "when acute care services are denied, so as to trigger the expedited reconsideration process, services must continue until a final reconsideration decision has been issued." (Judgment at 5, ¶ (e).) It would seem to the Court that within the medical profession there must be some general consensus regarding what types of

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[1] *See* Defendant's Motion for Stay at 10 ("The requirement that written notice be given within five working days of any 'oral request' for services is also problematic. (2d Fried Decl. ¶ 8.) The practice of medicine routinely involves give-and-take discussions between doctors and patients about treatment options, and it may be difficult at times to determine whether an enrollee is merely asking questions about the availability of alternative treatments, or is making an 'oral request' to which a detailed written notice must be provided within five days. At the very least, HCFA feels that further consideration is necessary before imposition of such a requirement, which would greatly increase the amount of physician time spent on documenting each and every treatment choice—time that could otherwise be spent providing patient care. *Id.* ¶¶ 8, 12.")

conditions are considered "acute," and that the parties should be able to develop a workable definition for purposes of implementing the Judgment. Ultimately, the Court could make this determination, but only after hearing testimony from medical experts on the subject.

This Court finds that many of the Secretary's problematic objections to the Judgment are self inflicted. The Secretary chooses to construe the Judgment in such a fashion so as to create unnecessary problems. This Court drafted the Judgment to allow for flexibility in its implementation. (Judgment filed May 3, 1997 at 3 n.4).

The standard for granting a stay pending appeal is similar to the standard for granting a preliminary injunction in this Circuit. *Nevada Airlines, Inc. v. Bond*, 622 F.2d 1017, 1018 n.3 (9th Cir. 1980). To obtain a stay, "the moving party must demonstrate either a combination of probable success on the merits and the possibility of irreparable injury or that serious questions are raised and the balance of hardships tips sharply in the moving party's favor." *Beltran v. Meyers*, 677 F.2d 1317, 1320 (9th Cir. 1982). These tests are merely the extremes of a continuum so that as one factor increases in weight the other decreases. *Brenda v. Grand Lodge of International Ass'n. of Machinists*, 584 F.2d 308, 314 (9th Cir. 1978).

The Court finds that the hardships faced by the Plaintiffs outweigh those of the Defendant, but that the entire case may become largely moot if the Secretary's attestations regarding rule changes are true and are implemented without delay.

Accordingly,

IT IS ORDERED that Defendant's Motion for Stay Pending Appeal, filed May 12, 1997, is GRANTED.

DATED this 10th day of June, 1997.

/s/ ALFREDO C. MARQUEZ
ALFREDO C. MARQUEZ
Senior U. S. District Judge

APPENDIX F

The Balanced Budget Act of 1997, Public Law No. 105-33, Sections 4001-4002, 111 Stat. 275-330, provides in relevant part as follows:

SEC. 4001. ESTABLISHMENT OF MEDICARE+CHOICE PROGRAM.

"SEC. 1851. (a) CHOICE OF MEDICARE BENEFITS THROUGH MEDICARE+CHOICE PLANS—

"(1) IN GENERAL.—Subject to the provisions of this section, each Medicare+Choice eligible individual (as defined in paragraph (3)) is entitled to elect to receive benefits under this title—

"(A) through the original medicare fee-for-service program under parts A and B, or

"(B) through enrollment in a Medicare+Choice plan under this part.

"(2) TYPES OF MEDICARE+CHOICE PLANS THAT MAY BE AVAILABLE.—A Medicare+Choice plan may be any of the following types of plans of health insurance:

"(A) COORDINATED CARE PLANS.—Coordinated care plans which provide health care services, including but not limited to health maintenance organization plans (with or without point of service options), plans offered by provider-sponsored organizations (as defined in section 1855(d)), and preferred provider organization plans.

"(B) COMBINATION OF MSA PLAN AND CONTRIBUTIONS TO MEDICARE+CHOICE MSA.—An MSA plan, as defined in section 1859(b)(3), and a contribution into a Medicare+Choice medical savings account (MSA).

"(C) PRIVATE FEE-FOR-SERVICE PLANS.—A Medicare+Choice private fee-for-service plan, as defined in section 1859(b)(2).

"(3) MEDICARE+CHOICE ELIGIBLE INDIVIDUAL.—

"(A) IN GENERAL.—In this title, subject to subparagraph (B), the term 'Medicare+Choice eligible individual' means an individual who is entitled to benefits under part A and enrolled under part B.

"(B) SPECIAL RULE FOR END-STAGE RENAL DISEASE.—Such term shall not include an individual medically determined to have end-stage renal disease, except that an individual who develops end-stage renal disease while enrolled in a Medicare+Choice plan may continue to be enrolled in that plan.

* * * * *

"(d) PROVIDING INFORMATION TO PROMOTE INFORMED CHOICE.—

"(1) IN GENERAL.—The Secretary shall provide for activities under this subsection to broadly disseminate information to medicare beneficiaries (and prospective medicare beneficiaries) on the coverage options pro-

vided under this section in order to promote an active, informed selection among such options.

"(2) PROVISION OF NOTICE.—

"(A) OPEN SEASON NOTIFICATION.—At least 15 days before the beginning of each annual, coordinated election period (as defined in sub section (e)(3)(B)), the Secretary shall mail to each Medicare+Choice eligible individual residing in an area the following:

"(i) GENERAL INFORMATION.—The general information described in paragraph (3).

"(ii) LIST OF PLANS AND COMPARISON OF PLAN OPTIONS.—A list identifying the Medicare+Choice plans that are (or will be) available to residents of the area and information described in paragraph (4) concerning such plans. Such information shall be presented in a comparative form.

"(iii) ADDITIONAL INFORMATION.—Any other information that the Secretary determines will assist the individual in making the election under this section.

The mailing of such information shall be coordinated, to the extent practicable, with the mailing of any annual notice under section 1804.

"(B) NOTIFICATION TO NEWLY ELIGIBLE MEDICARE+CHOICE ELIGIBLE INDIVIDUALS.—To the extent practicable, the Secretary shall, not later than 30 days before the beginning of the initial Medicare+Choice enrollment period for an individ-

ual described in subsection (e)(1), mail to the individual the information described in subparagraph (A).

"(C) FORM.—The information disseminated under this paragraph shall be written and formatted using language that is easily understandable by medicare beneficiaries.

"(D) PERIODIC UPDATING.—The information described in subparagraph (A) shall be updated on at least an annual basis to reflect changes in the availability of Medicare+Choice plans and the benefits and Medicare+Choice monthly basic and supplemental beneficiary premiums for such plans.

"(3) GENERAL INFORMATION.—General information under this paragraph, with respect to coverage under this part during a year, shall include the following:

"(A) BENEFITS UNDER ORIGINAL MEDICARE FEE-FOR-SERVICE PROGRAM OPTION.—A general description of the benefits covered under the original medicare fee-for-service program under parts A and B, including—

"(i) covered items and services,

"(ii) beneficiary cost sharing, such as deductibles, coinsurance, and copayment amounts, and

"(iii) any beneficiary liability for balance billing.

"(B) ELECTION PROCEDURES.—Information and instructions on how to exercise election options under this section.

"(C) RIGHTS.—A general description of procedural rights (including grievance and appeals procedures) of beneficiaries under the original medicare fee-for-service program and the Medicare+Choice program and the right to be protected against discrimination based on health status-related factors under section 1852(b).

"(D) INFORMATION ON MEDIGAP AND MEDICARE SELECT.—A general description of the benefits, enrollment rights, and other requirements applicable to medicare supplemental policies under section 1882 and provisions relating to medicare select policies described in section 1882(t).

"(E) POTENTIAL FOR CONTRACT TERMINATION.—The fact that a Medicare+Choice organization may terminate its contract, refuse to renew its contract, or reduce the service area included in its contract, under this part, and the effect of such a termination, nonrenewal, or service area reduction may have on individuals enrolled with the Medicare+Choice plan under this part.

"(4) INFORMATION COMPARING PLAN OPTIONS.—Information under this paragraph, with respect to a Medicare+Choice plan for a year, shall include the following:

"(A) BENEFITS.—The benefits covered under the plan, including the following:

"(i) Covered items and services beyond those provided under the original medicare fee-for-service program.

"(ii) Any beneficiary cost sharing.

"(iii) Any maximum limitations on out-of-pocket expenses.

"(iv) In the case of an MSA plan, differences in cost sharing, premiums, and balance billing under such a plan compared to under other Medicare+Choice plans.

"(v) In the case of a Medicare+Choice private fee-for-service plan, differences in cost sharing, premiums, and balance billing under such a plan compared to under other Medicare+Choice plans.

"(vi) The extent to which an enrollee may obtain benefits through out-of-network health care providers.

"(vii) The extent to which an enrollee may select among in-network providers and the types of providers participating in the plan's network.

"(viii) The organization's coverage of emergency and urgently needed care.

"(B) PREMIUMS.—The Medicare+Choice monthly basic beneficiary premium and Medicare+Choice monthly supplemental beneficiary premium, if any, for the plan or, in the case of an MSA plan, the Medicare+Choice monthly MSA premium.

"(C) SERVICE AREA.—The service area of the plan.

"(D) QUALITY AND PERFORMANCE.—To the extent available, plan quality and performance indicators for the benefits under the plan (and how they compare to such indicators under the original medicare fee-for-service program under parts A and B in the area involved), including—

"(i) disenrollment rates for medicare enrollees electing to receive benefits through the plan for the previous 2 years (excluding disenrollment due to death or moving outside the plan's service area),

"(ii) information on medicare enrollee satisfaction,

"(iii) information on health outcomes, and

"(iv) the recent record regarding compliance of the plan with requirements of this part (as determined by the Secretary).

"(E) SUPPLEMENT BENEFITS.—Whether the organization offering the plan includes mandatory supplemental benefits in its base benefit package or offers optional supplemental benefits and the terms and conditions (including premiums) for such coverage.

"(5) MAINTAINING A TOLL-FREE NUMBER AND INTERNET SITE.—The Secretary shall maintain a toll-free number for inquiries regarding Medicare+Choice options and the operation of this part in all areas

in which Medicare+Choice plans are offered and an Internet site through which individuals may electronically obtain information on such options and Medicare+Choice plans.

"(6) USE OF NON-FEDERAL ENTITIES.—The Secretary may enter into contracts with non-Federal entities to carry out activities under this subsection.

"(7) PROVISION OF INFORMATION.—A Medicare+Choice organization shall provide the Secretary with such information on the organization and each Medicare+Choice plan it offers as may be required for the preparation of the information referred to in paragraph (2)(A).

"(e) COVERAGE ELECTION PERIODS.—

"(1) INITIAL CHOICE UPON ELIGIBILITY TO MAKE ELECTION IF MEDICARE+CHOICE PLANS AVAILABLE TO INDIVIDUAL.—If, at the time an individual first becomes entitled to benefits under part A and enrolled under part B, there is one or more Medicare+Choice plans offered in the area in which the individual resides, the individual shall make the election under this section during a period specified by the Secretary such that if the individual elects a Medicare+Choice plan during the period, coverage under the plan becomes effective as of the first date on which the individual may receive such coverage.

"(2) OPEN ENROLLMENT AND DISENROLLMENT OPPORTUNITIES.—Subject to paragraph (5)—

"(A) CONTINUOUS OPEN ENROLLMENT AND DISENROLLMENT THROUGH 2001.—At any time during 1998, 1999, 2000, and 2001, a Medicare+Choice eligile individual may change the election under subsection (a)(1).

* * * * *

"(f)" EFFECTIVENESS OF ELECTIONS AND CHANGES OF ELECTIONS.—

"(1) DURING INITIAL COVERAGE ELECTION PERIOD.—An election of coverage made during the initial coverage election period under subsection (e)(1)(A) shall take effect upon the date the individual becomes entitled to benefits under part A and enrolled under part B, except as the Secretary may provide (consistent with section 1838) in order to prevent retroactive coverage.

"(2) DURING CONTINUOUS OPEN ENROLLMENT PERIODS.—An election or change of coverage made under subsection (e)(2) shall take effect with the first day of the first calendar month following the date on which the election is made.

* * * * *

"BENEFITS AND BENEFICIARY PROTECTIONS"

"SEC. 1852. (a) BASIC BENEFITS.—

"(1) IN GENERAL.—Except as provided in section 1859(b)(3) for MSA plans, each Medicare+Choice plan shall provide to members enrolled under this part, through providers and other persons that meet the applicable requirements of this title and part A of title XI—

"(A) those items and services (other than hospice care) for which benefits are available under parts A and B to individuals residing in the area served by the plan, and

"(B) additional benefits required under section 1854(f)(1)(A).

"(2) SATISFACTION OF REQUIREMENT.—

"(A) IN GENERAL.—A Medicare+Choice plan (other than an MSA plan) offered by a Medicare+Choice organization satisfies paragraph (1)(A), with respect to benefits for items and services furnished other than through a provider or other person that has a contract with the organization offering the plan, if the plan provides payment in an amount so that—

"(i) the sum of such payment amount and any cost sharing provided for under the plan, is equal to at least

"(ii) the total dollar amount of payment for such items and services as would otherwise be authorized under parts A and B (including any balance billing permitted under such parts).

"(B) REFERENCE TO RELATED PROVISIONS.—For provision relating to—

"(i) limitations on balance billing against Medicare+Choice organizations for non-contract providers, see sections 1852(k) and 1866(a)(1)(O), and

"(ii) limiting actuarial value of enrollee liability for covered benefits, see section 1854(e).

"(3) SUPPLEMENT BENEFITS.—

"(A) BENEFITS INCLUDED SUBJECT TO SECRETARY'S APPROVAL.—Each Medicare+Choice organization may provide to individuals enrolled under this part, other than under an MSA plan, (without affording those individuals an option to decline the coverage) supplemental health care benefits that the Secretary may approve. The Secretary shall approve any such supplemental benefits unless the Secretary determines that including such supplemental benefits would substantially discourage enrollment by Medicare+Choice eligible individuals with the organization.

"(B) AT ENROLLEES' OPTION.—

"(i) IN GENERAL.—Subject to clause (ii), a Medicare+Choice organization may provide to individuals enrolled under this part supplemental health care benefits that the individuals may elect, at their option, to have covered.

"(ii) SPECIAL RULE FOR MSA PLANS.—A Medicare+Choice organization may not provide, under an MSA plan, supplemental health care benefits that cover the deductible described in

section 1859(b)(2)(B). In applying the previous sentence, health benefits described in section 1882(u)(2)(B) shall not be treated as covering such deductible.

"(C) APPLICATION TO MEDICARE+CHOICE PRIVATE FEE-FOR-SERVICE PLANS.—Nothing in this paragraph shall be construed as preventing a Medicare+Choice private fee-for-service plan from offering supplemental benefits that include payment for some or all of the balance billing amounts permitted consistent with section 1852(k) and coverage of additional services that the plan finds to be medically necessary.

"(4) ORGANIZATION AS SECONDARY PAYER.—Notwithstanding any other provision of law, a Medicare+Choice organization may (in the case of the provision of items and services to an individual under a Medicare+Choice plan under circumstances in which payment under this title is made secondary pursuant to section 1862(b)(2)) charge or authorize the provider of such services to charge, in accordance with the charges allowed under a law, plan, or policy described in such section—

"(A) the insurance carrier, employer, or other entity which under such law, plan, or policy is to pay for the provision of such services, or

"(B) such individual to the extent that the individual has been paid under such law, plan, or policy for such services.

"(5) NATIONAL COVERAGE DETERMINATIONS.—If there is a national coverage determination made in the period beginning on the date of an announcement under section 1853(b) and ending on the date of the next

announcement under such section and the Secretary projects that the determination will result in a significant change in the costs to a Medicare+Choice organization of providing the benefits that are the subject of such national coverage determination and that such change in costs was not incorporated in the determination of the annual Medicare+Choice capitation rate under section 1853 included in the announcement made at the beginning of such period, then, unless otherwise required by law—

"(A) such determination shall not apply to contracts under this part until the first contract year that begins after the end of such period, and

"(B) if such coverage determination provides for coverage of additional benefits or coverage under additional circumstances, section 1851(i)(1) shall not apply to payment for such additional benefits or benefits provided under such additional circumstances until the first contract year that begins after the end of such period.

"(b) ANTIDISCRIMINATION.—

"(1) BENEFICIARIES.—

"(A) IN GENERAL.—A Medicare+Choice organization may not deny, limit, or condition the coverage or provision of benefits under this part, for individuals permitted to be enrolled with the organization under this part, based on any health status-related factor described in section 2702(a)(1) of the Public Health Service Act.

"(B) CONSTRUCTION.—Subparagraph (A) shall not be construed as requiring a Medicare+Choice organization to enroll individuals who are

determined to have end-stage renal disease, except as provided under section 1851(a)(3)(B).

"(2) PROVIDERS.—A Medicare+Choice organization shall not discriminate with respect to participation, reimbursement, or indemnification as to any provider who is acting within the scope of the provider's license or certification under applicable State law, solely on the basis of such license or certification. This paragraph shall not be construed to prohibit a plan from including providers only to the extent necessary to meet the needs of the plan's enrollees or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan.

"(c) DISCLOSURE REQUIREMENTS.—

"(1) DETAILED DESCRIPTION OF PLAN PROVISIONS.—A Medicare+Choice organization shall disclose, in clear, accurate, and standardized form to each enrollee with a Medicare+Choice plan offered by the organization under this part at the time of enrollment and at least annually thereafter, the following information regarding such plan:

"(A) SERVICE AREA.—The plan's service area.

"(B) BENEFITS.—Benefits offered under the plan, including information described in section 1851(d)(3)(A) and exclusions from coverage and, if it is an MSA plan, a comparison of benefits under such a plan with benefits under other Medicare+Choice plans.

"(C) ACCESS.—The number, mix, and distribution of plan providers, out-of-network coverage (if any) provided by the plan, and any point-of-service option (including the supplemental premium for such option).

"(D) OUT OF AREA COVERAGE.—Out-of-area coverage provided by the plan.

"(E) EMERGENCY COVERAGE.—Coverage of emergency services, including—

"(i) the appropriate use of emergency services, including use of the 911 telephone system or its local equivalent in emergency situations and an explanation of what constitutes an emergency situation;

"(ii) the process and procedures of the plan for obtaining emergency services; and

"(iii) the locations of (I) emergency departments, and (II) other settings, in which plan physicians and hospitals provide emergency services and post-stabilization care.

"(F) SUPPLEMENTAL BENEFITS.—Supplemental benefits available from the organization offering the plan, including—

"(i) whether the supplemental benefits are optional,

"(ii) the supplemental benefits covered, and

"(iii) the Medicare+Choice monthly supplemental beneficiary premium for the supplemental benefits.

"(G) PRIOR AUTHORIZATION RULES.—Rules regarding prior authorization or other review requirements that could result in nonpayment.

"(H) PLAN GRIEVANCE AND APPEALS PROCEDURES.—All plan appeal or grievance rights and procedures.

"(I) QUALITY ASSURANCE PROGRAM.—A description of the organization's quality assurance program under subsection (e).

"(2) DISCLOSURE UPON REQUEST.—Upon request of a Medicare+Choice eligible individual, a Medicare+Choice organization must provide the following information to such individual:

"(A) The general coverage information and general comparative plan information made available under clauses (i) and (ii) of section 1851(d)(2)(A).

"(B) Information on procedures used by the organization to control utilization of services and expenditures.

"(C) Information on the number of grievances, redeterminations, and appeals and on the disposition in the aggregate of such matters.

"(D) An overall summary description as to the method of compensation of participating physicians.

"(d) ACCESS TO SERVICES.—

"(1) IN GENERAL.—A Medicare+Choice organization offering a Medicare+Choice plan may select the providers from whom the benefits under the plan are provided so long as—

"(A) the organization makes such benefits available and accessible to each individual electing the plan within the plan service area with reasonable promptness and in a manner which assures continuity in the provision of benefits;

"(B) when medically necessary the organization makes such benefits available and accessible 24 hours a day and 7 days a week;

"(C) the plan provides for reimbursement with respect to services which are covered under subparagraphs (A) and (B) and which are provided to such an individual other than through the organization, if—

"(i) the services were not emergency services (as defined in paragraph (3)), but (I) the services were medically necessary and immediately required because of an unforeseen illness, injury, or condition, and (II) it was not reasonable given the circumstances to obtain the services through the organization,

"(ii) the services were renal dialysis services and were provided other than through the organization because the individual was temporarily out of the plan's service area, or

"(iii) the services are maintenance care or post-stabilization care covered

under the guidelines established under paragraph (2);

"(D) the organization provides access to appropriate providers, including credentialed specialists, for medically necessary treatment and services; and

"(E) coverage is provided for emergency services (as defined in paragraph (3)) without regard to prior authorization or the emergency care provider's contractual relationship with the organization.

"(2) GUIDELINES RESPECTING COORDINATION OF POST-STABILIZATION CARE.—A Medicare+Choice plan shall comply with such guidelines as the Secretary may prescribe relating to promoting efficient and timely coordination of appropriate maintenance and post-stabilization care of an enrollee after the enrollee has been determined to be stable under section 1867.

"(3) DEFINITION OF EMERGENCY SERVICES.—In this subsection—

"(A) IN GENERAL.—The term 'emergency services' means, with respect to an individual enrolled with an organization, covered inpatient and outpatient services that—

"(i) are furnished by a provider that is qualified to furnish such services under this title, and

"(ii) are needed to evaluate or stabilize an emergency medical condition (as defined in subparagraph (B)).

"(B) EMERGENCY MEDICAL CONDITION BASED ON PRUDENT LAYPERSON.—The term 'emergency medical condition' means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

"(i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy,

"(ii) serious impairment to bodily functions, or

"(iii) serious dysfunction of any bodily organ or part.

"(4) ASSURING ACCESS TO SERVICES IN MEDICARE+CHOICE PRIVATE FEE-FOR-SERVICE PLANS.—In addition to any other requirements under this part, in the case of a Medicare+Choice private fee-for-service plan, the organization offering the plan must demonstrate to the Secretary that the organization has sufficient number and range of health care professionals and providers willing to provide services under the terms of the plan. The Secretary shall find that an organization has met such requirement with respect to any category of health care professional or provider if, with respect to that category of provider—

"(A) the plan has established payment rates for covered services furnished by that category of provider that are not less than the payment rates provided for under part A, part B, or both, for such services, or

"(B) the plan has contracts or agreements with a sufficient number and range of providers within such category to provide covered services under the terms of the plan,

or a combination of both. The previous sentence shall not be construed as restricting the persons from whom enrollees under such a plan may obtain covered benefits.

"(e) QUALITY ASSURANCE PROGRAM.—

"(1) IN GENERAL.—Each Medicare+Choice organization must have arrangements, consistent with any regulation, for an ongoing quality assurance program for health care services it provides to individuals enrolled with Medicare+Choice plans of the organization.

"(2) ELEMENTS OF PROGRAM.—

"(A) IN GENERAL.—The quality assurance program of an organization with respect to a Medicare+Choice plan (other than a Medicare+Choice private fee-for-service plan or a non-network MSA plan) it offers shall—

"(i) stress health outcomes and provide for the collection, analysis, and reporting of data (in accordance with a quality measurement system that the

Secretary recognizes) that will permit measurement of outcomes and other indices of the quality of Medicare+Choice plans and organizations;

"(ii) monitor and evaluate high volume and high risk services and the care of acute and chronic conditions;

"(iii) evaluate the continuity and coordination of care that enrollees receive;

"(iv) be evaluated on an ongoing basis as to its effectiveness;

"(v) include measures of consumer satisfaction;

"(vi) provide the Secretary with such access to information collected as may be appropriate to monitor and ensure the quality of care provided under this part;

"(vii) provide review by physicians and other health care professionals of the process followed in the provision of such health care services;

"(viii) provide for the establishment of written protocols for utilization review, based on current standards of medical practice;

"(ix) have mechanisms to detect both underutilization and overutilization of services;

"(x) after identifying areas for improvement, establish or alter practice parameters;

"(xi) take action to improve quality and assesses the effectiveness of such action through systematic followup; and

"(xii) make available information on quality and outcomes measures to facilitate beneficiary comparison and choice of health coverage options (in such form and on such quality and outcomes measures as the Secretary determines to be appropriate).

"(B) ELEMENTS OF PROGRAM FOR ORGANIZATIONS OFFERING MEDICARE+CHOICE PRIVATE FEE-FOR-SERVICE PLANS AND NON-NETWORK MSA PLANS.—The quality assurance program of an organization with respect to a Medicare+Choice private fee-for-service plan or a non-network MSA plan it offers shall—

"(i) meet the requirements of clauses (i) through (vi) of subparagraph (A);

"(ii) insofar as it provides for the establishment of written protocols for utilization review, base such protocols on current standards of medical practice; and

"(iii) have mechanisms to evaluate utilization of services and inform providers and enrollees of the results of such evaluation.

"(C) DEFINITION OF NON-NETWORK MSA PLAN.—In this subsection, the term 'non-network MSA plan' means an MSA plan offered by a Medicare+Choice organization that does not provide

benefits required to be provided by this part, in whole or in part, through a defined set of providers under contract, or under another arrangement, with the organization.

"(3) EXTERNAL REVIEW.—

"(A) IN GENERAL.—Each Medicare+Choice organization shall, for each Medicare+Choice plan it operates, have an agreement with an independent quality review and improvement organization approved by the Secretary to perform functions of the type described in sections 1154(a)(4)(B) and 1154(a)(14) with respect to services furnished by Medicare+Choice plans for which payment is made under this title. The previous sentence shall not apply to a Medicare+Choice private fee-for-service plan or a non-network MSA plan that does not employ utilization review.

"(B) NONDUPLICATION OF ACCREDITATION. —Except in the case of the review of quality complaints, and consistent with subparagraph (C), the Secretary shall ensure that the external review activities conducted under subparagraph (A) are not duplicative of review activities conducted as part of the accreditation process.

"(C) WAIVER AUTHORITY.—The Secretary may waive the requirement described in subparagraph (A) in the case of an organization if the Secretary determines that the organization has consistently maintained an excellent record of quality assurance and compliance with other requirements under this part.

"(4) TREATMENT OF ACCREDITATION.—The Secretary shall provide that a Medicare+Choice organization

is deemed to meet requirements of paragraphs (1) and (2) of this subsection and subsection (h) (relating to confidentiality and accuracy of enrollee records) if the organization is accredited (and periodically re-accredited) by a private organization under a process that the Secretary has determined assures that the organization, as a condition of accreditation, applies and enforces standards with respect to the requirements involved that are no less stringent than the standards established under section 1856 to carry out the respective requirements.

"(f) GRIEVANCE MECHANISM.—Each Medicare+Choice organization must provide meaningful procedures for hearing and resolving grievances between the organization (including any entity or individual through which the organization provides health care services) and enrollees with Medicare+Choice plans of the organization under this part.

"(g) COVERAGE DETERMINATIONS, RECONSIDERATIONS, AND APPEALS.—

"(1) DETERMINATIONS BY ORGANIZATION.—

"(A) IN GENERAL.—A Medicare+Choice organization shall have a procedure for making determinations regarding whether an individual enrolled with the plan of the organization under this part is entitled to receive a health service under this section and the amount (if any) that the individual is required to pay with respect to such service. Subject to paragraph (3), such procedures shall provide for such determination to be made on a timely basis.

"(B) EXPLANATION OF DETERMINATION.—Such a determination that denies coverage, in whole in part, shall be in writing and shall include a statement in understandable language of the reasons for the denial and a description of the reconsideration and appeals processes.

"(2) RECONSIDERATIONS.—

"(A) IN GENERAL.—The organization shall provide for reconsideration of a determination described in paragraph (1)(B) upon request by the enrollee involved. The reconsideration shall be within a time period specified by the Secretary, but shall be made, subject to paragraph (3), not later than 60 days after the date of the receipt of the request for reconsideration.

"(B) PHYSICIAN DECISION ON CERTAIN RECONSIDERATIONS.—A reconsideration relating to a determination to deny coverage based on a lack of medical necessity shall be made only by a physician with appropriate expertise in the field of medicine which necessitates treatment who is other than a physician involved in the initial determination.

"(3) EXPEDITED DETERMINATIONS AND RECONSIDERATIONS.—

"(A) RECEIPT OF REQUESTS.—

"(i) ENROLLEE REQUESTS.—An enrollee in a Medicare+Choice plan may request, either in writing or orally, an expedited determination under paragraph (1) or an expedited reconsideration under paragraph (2) by the Medicare+Choice organization.

"(ii) PHYSICIAN REQUESTS.—A physician, regardless whether the physician is affiliated with the organization or not, may request, either in writing or orally, such an expedited determination or reconsideration.

"(B) ORGANIZATION PROCEDURES.—

"(i) IN GENERAL.—The Medicare+Choice organization shall maintain procedures for expediting organization determinations and reconsiderations when, upon request of an enrollee, the organization determines that the application of the normal time frame for making a determination (or a reconsideration involving a determination) could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

"(ii) EXPEDITION REQUIRED FOR PHYSICIAN REQUESTS.—In the case of a request for an expedited determination or reconsideration made under subparagraph (A)(ii), the organization shall expedite the determination or reconsideration if the request indicates that the application of the normal time frame for making a determination (or a reconsideration involving a determination) could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

"(iii) TIMELY RESPONSE.—In cases described in clauses (i) and (ii), the organi-

zation shall notify the enrollee (and the physician involved, as appropriate) of the determination or reconsideration under time limitations established by the Secretary, but not later than 72 hours of the time of receipt of the request for the determination or reconsideration (or receipt of the information necessary to make the determination or reconsideration), or such longer period as the Secretary may permit in specified cases.

"(4) INDEPENDENT REVIEW OF CERTAIN COVERAGE DENIALS—The Secretary shall contract with an independent, outside entity to review and resolve in a timely manner reconsiderations that affirm denial of coverage, in whole or in part.

"(5) APPEALS.—An enrollee with a Medicare+Choice plan of a Medicare+Choice organization under this part who is dissatisfied by reason of the enrollee's failure to receive any health service to which the enrollee believes the enrollee is entitled and at no greater charge than the enrollee believes the enrollee is required to pay is entitled, if the amount in controversy is $100 or more, to a hearing before the Secretary to the same extent as is provided in section 205(b), and in any such hearing the Secretary shall make the organization a party. If the amount in controversy is $1,000 or more, the individual or organization shall, upon notifying the other party, be entitled to judicial review of the Secretary's final decision as provided in section 205(g), and both the individual and the organization shall be entitled to be parties to that judicial

review. In applying subsections (b) and (g) of section 205 as provided in this paragraph, and in applying section 205(l) thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

"(h) CONFIDENTIALITY AND ACCURACY OF ENROLLEE RECORDS.—Insofar as a Medicare+Choice organization maintains medical records or other health information regarding enrollees under this part, the Medicare+Choice organization shall establish procedures—

"(1) to safeguard the privacy of any individually identifiable enrollee information;

"(2) to maintain such records and information in a manner that is accurate and timely, and

"(3) to assure timely access of enrollees to such records and information.

"(i) INFORMATION ON ADVANCE DIRECTIVES.—Each Medicare+Choice organization shall meet the requirement of section 1866(f) (relating to maintaining written policies and procedures respecting advance directives).

"(j) RULES REGARDING PROVIDER PARTICIPATION.—

"(1) PROCEDURES.—Insofar as a Medicare+Choice organization offers benefits under a Medicare+Choice plan through agreements with physicians, the organization shall establish reasonable procedures relating to the participation

(under an agreement between a physician and the organization) of physicians under such a plan. Such procedures shall include—

"(A) providing notice of the rules regarding participation,

"(B) providing written notice of participation decisions that are adverse to physicians, and

"(C) providing a process within the organization for appealing such adverse decisions, including the presentation of information and views of the physician regarding such decision.

"(2) CONSULTATION IN MEDICAL POLICIES.—A Medicare+Choice organization shall consult with physicians who have entered into participation agreements with the organization regarding the organization's medical policy, quality, and medical management procedures.

"(3) PROHIBITING INTERFERENCE WITH PROVIDER ADVICE TO ENROLLEES.—

"(A) IN GENERAL.—Subject to subparagraphs (B) and (C), a Medicare+Choice organization (in relation to an individual enrolled under a Medicare+Choice plan offered by the organization under this part) shall not prohibit or otherwise restrict a covered health care professional (as defined in subparagraph (D)) from advising such an individual who is a patient of the professional

about the health status of the individual or medical care or treatment for the individual's condition or disease, regardless of whether benefits for such care or treatment are provided under the plan, if the professional is acting within the lawful scope of practice.

"(B) CONSCIENCE PROTECTION.—Subparagraph (A) shall not be construed as requiring a Medicare+Choice plan to provide, reimburse for, or provide coverage of a counseling or referral service if the Medicare+Choice organization offering the plan—

"(i) objects to the provision of such service on moral or religious grounds; and

"(ii) in the manner and through the written instrumentalities such Medicare+Choice organization deems appropriate, makes available information on its policies regarding such service to prospective enrollees before or during enrollment and to enrollees within 90 days after the date that the organization or plan adopts a change in policy regarding such a counseling or referral service.

"(C) CONSTRUCTION.—Nothing in subparagraph (B) shall be construed to affect disclosure requirements under State law or under the Employee Retirement Income Security Act of 1974.

* * * * *

SEC. 4002. TRANSITIONAL RULES FOR CURRENT MEDICARE HMO PROGRAM.

* * * * *

(b) TRANSITION.—

(1) RISK-SHARING CONTRACTS.—Section 1876 (42 U.S.C. 1395mm) is amended by adding at the end the following new subsections:

"(k)(1) Except as provided in paragraph (2)—

"(A) on or after the date standards for Medicare+Choice organizations and plans are first established under section 1856(b)(1), the Secretary shall not enter into any risk-sharing contract under this section with an eligible organization; and

"(B) for any contract year beginning on or after January 1, 1999, the Secretary shall not renew any such contract.

"(2) An individual who is enrolled in part B only and is enrolled in an eligible organization with a risk-sharing contract under this section on December 31, 1998, may continue enrollment in such organization in accordance with regulations described in section 1856(b)(1).

"(3) Notwithstanding subsection (a), the Secretary shall provide that payment amounts under risk-sharing contracts under this section for months in a year (beginning with January 1998) shall be computed—

"(A) with respect to individuals entitled to benefits under both parts A and B, by substituting payment rates under section 1853(a) for the payment rates otherwise established under section 1876(a), and

"(B) with respect to individuals only entitled to benefits under part B, by substituting an appropriate proportion of such rates (reflecting the relative proportion of payments under this title attributable to such part) for the payment rates otherwise established under subsection (a).

APPENDIX G

Section 1395mm of Title 42, superseded in relevant part by Sections 4001-4002 of the Balanced Budget Act of 1997, Public Law No. 105-33, 111 Stat. 275-330, provides in pertinent part:

§ 1395mm. Payments to health maintenance organizations and competitive medical plans

* * * * *

(c) Enrollment in plan; duties of organization to enrollees

(1) The Secretary may not enter into a contract under this section with an eligible organization unless it meets the requirements of this subsection and subsection (e) of this section with respect to members enrolled under this section.

(2)(A) The organization must provide to members enrolled under this section, through providers and other persons that meet the applicable requirements of this subchapter and part A of subchapter XI of this chapter—

(i) only those services covered under parts A and B of this subchapter, for those members entitled to benefits under part A of this subchapter and enrolled under part B of this subchapter, or

(ii) only those services covered under part B of this subchapter, for those members enrolled only under such part,

which are available to individuals residing in the geographic area served by the organization, except that (I) the organization may provide such members with such additional health care services as the members may elect, at their option, to have covered, and (II) in the case of an organization with a risk-sharing contract, the organization may provide such members with such additional health care services as the Secretary may approve. The Secretary shall approve any such additional health care services which the organization proposes to offer to such members, unless the Secretary determines that including such additional services will substantially discourage enrollment by covered individuals with the organization.

* * * * *

(3)(A)(1) Each eligible organization must have an open enrollment period, for the enrollment of individuals under this section, of at least 30 days duration every year . . . .

* * * * *

(B) An individual may enroll under this section with an eligible organization in such manner as may be prescribed in regulations and may terminate his enrollment with the eligible organization as of the beginning of the first calendar month following the date on which the request is made for such termination (or, in the case of financial insolvency of the organization, as may be

prescribed by regulations) or, in the case of such an organization with a reasonable cost reimbursement contract, as may be prescribed by regulations. In the case of an individual's termination of enrollment, the organization shall provide the individual with a copy of the written request for termination of enrollment and a written explanation of the period (ending on the effective date of the termination) during which the individual continues to be enrolled with the organization and may not receive benefits under this subchapter other than through the organization.

* * * * *

(5)(A) The organization must provide meaningful procedures for hearing and resolving grievances between the organization (including any entity or individual through which the organization provides health care services) and members enrolled with the organization under this section.

(B) A member enrolled with an eligible organization under this section who is dissatisfied by reason of his failure to receive any health service to which he believes he is entitled and at no greater charge than he believes he is required to pay is entitled, if the amount in controversy is $100 or more, to a hearing before the Secretary to the same extent as is provided in section 405(b) of this title, and in any such hearing the Secretary shall make the eligible organization a party. If the amount in controversy is $1,000 or more, the individual or eligible organization shall, upon notifying the other party, be entitled to judicial review of the Secretary's final decision as provided in section 405(g) of this title, and both the individual and the eligible organization

shall be entitled to be parties to that judicial review. In applying sections 405(b) and 405(g) of this title as provided in this subparagraph, and in applying section 405(l) of this title thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

(6) The organization must have arrangements, established in accordance with regulations of the Secretary, for an ongoing quality assurance program for health care services it provides to such individuals, which program (A) stresses health outcomes and (B) provides review by physicians and other health care professionals of the process followed in the provision of such health care services.

(7) A risk-sharing contract under this section shall provide that in the case of an individual who is receiving inpatient hospital services from a subsection (d) hospital (as defined in section 1395ww(d)(1)(B) of this title) as of the effective date of the individual's—

(A) enrollment with an eligible organization under this section—

(i) payment for such services until the date of the individual's discharge shall be made under this subchapter as if the individual were not enrolled with the organization,

(ii) the organization shall not be financially responsible for payment for such services until the date after the date of the individual's discharge, and

(iii) the organization shall nonetheless be paid the full amount otherwise payable to the organization under this section; or

(B) termination of enrollment with an eligible organization under this section—

(i) the organization shall be financially responsible for payment for such services after such date and until the date of the individual's discharge,

(ii) payment for such services during the stay shall not be made under section 1395ww(d) of this title, and

(iii) the organization shall not receive any payment with respect to the individual under this section during the period the individual is not enrolled.

(8) A contract under this section shall provide that the eligible organization shall meet the requirement of section 1395cc(f) of this title (relating to maintaining written policies and procedures respecting advance directives).

(d) Right to enroll with contracting organization in geographic area

Subject to the provisions of subsection (c)(3) of this section, every individual entitled to benefits under part A of this subchapter and enrolled under part B of this subchapter or enrolled under part B of this subchapter only (other than an individual medically determined to have end-stage renal disease) shall be eligible to enroll under this section with any eligible organization with which the Secretary has entered into a

contract under this section and which serves the geographic area in which the individual resides.

* * * * *

(g) Risk-sharing contract

(1) The Secretary may enter a risk-sharing contract with any eligible organization, as defined in subsection (b) of this section, which has at least 5,000 members, except that the Secretary may enter into such a contract with an eligible organization that has fewer members if the organization primarily serves members residing outside of urbanized areas.

(2) Each risk-sharing contract shall provide that—

(A) if the adjusted community rate, as defined in subsection (e)(3) of this section, for services under parts A and B of this subchapter (as reduced for the actuarial value of the coinsurance and deductibles under those parts) for members enrolled under this section with the organization and entitled to benefits under part A of this subchapter and enrolled in part B of this subchapter, or

(B) if the adjusted community rate for services under part B of this subchapter (as reduced for the actuarial value of the coinsurance and deductibles under that part) for members enrolled under this section with the organization and entitled to benefits under part B of this subchapter only

is less than the average of the per capita rates of payment to be made under subsection (a)(1) of this sec-

tion at the beginning of an annual contract period for members enrolled under this section with the organization and entitled to benefits under part A of this subchapter and enrolled in part B of this subchapter, or enrolled in part B of this subchapter only, respectively, the eligible organization shall provide to members enrolled under a risk-sharing contract under this section with the organization and entitled to benefits under part A of this subchapter and enrolled in part B of this subchapter, or enrolled in part B of this subchapter only, respectively, the additional benefits described in paragraph (3) which are selected by the eligible organization and which the Secretary finds are at least equal in value to the difference between that average per capita payment and the adjusted community rate (as so reduced); except that this paragraph shall not apply with respect to any organization which elects to receive a lesser payment to the extent that there is no longer a difference between the average per capita payment and adjusted community rate (as so reduced) and except that an organization (with the approval of the Secretary) may provide that a part of the value of such additional benefits be withheld and reserved by the Secretary as provided in paragraph (5). If the Secretary finds that there is insufficient enrollment experience to determine an average of the per capita rates of payment to be made under subsection (a)(1) of this section at the beginning of a contract period, the Secretary may determine such an average based on the enrollment experience of other contracts entered into under this section.

* * * * *

(h) Reasonable cost reimbursement contract; requirements

(1) If—

(A) the Secretary is not satisfied that an eligible organization has the capacity to bear the risk of potential losses under a risk-sharing contract under this section, or

(B) the eligible organization so elects or has an insufficient number of members to be eligible to enter into a risk-sharing contract under subsection (g)(1) of this section.

the Secretary may, if he is otherwise satisfied that the eligible organization is able to perform its contractual obligations effectively and efficiently, enter into a contract with such organization pursuant to which such organization is reimbursed on the basis of its reasonable cost (as defined in section 1395x(v) of this title) in the manner prescribed in paragraph (3).

* * * * *

APPENDIX H

63 Fed. Reg. 34,968 (1998) (adding 42 C.F.R. 422.562-422.662), provides in relevant part as follows:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 400, 403, 410, 411, 417, and 422

[HCFA-1030-IFC]

RIN 0938-A129

Medicare Program; Establishment of the Medicare+ Choice Program

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Interim final rule with comment period.

* * * * *

42 CFR Chapter IV is amended as set forth below.

* * * * *

22. Subparts M through O are added to read as follows:

Subpart M—Grievances, Organization Determinations and Appeals

Sec.

422.560 Basis and scope.
422.561 Definitions.
422.562 General provisions.
422.564 Grievance procedures.
422.566 Organization determinations.
422.568 Standard timeframes and notice requirements for organization determinations.

422.570 Expediting certain organization determinations.
422.572 Timeframes and notice requirements for expedited organization determinations.
422.574 Parties to the organization determination.
422.576 Effect of an organization determination.
422.578 Right to a reconsideration.
422.580 Reconsideration defined.
422.582 Request for a standard reconsideration.
422.584 Expediting certain reconsiderations.
422.586 Opportunity to submit evidence.
422.590 Timeframes and responsibility for reconsiderations.
422.592 Reconsideration by an independent entity.
422.594 Notice of reconsidered determination by the independent entity.
422.596 Effect of a reconsidered determination.
422.600 Right to a hearing.
422.602 Request for an ALJ hearing.
422.608 Departmental Appeals Board review.
422.612 Judicial review.
422.616 Reopening and revising determinations and decisions.
422.618 How an M+C organization must effectuate reconsidered determinations or decisions.
422.620 How M+C organizations must notify enrollees of noncoverage of inpatient hospital care.
422.622 Requesting immediate PRO review of noncoverage of inpatient hospital care.

* * * * *

Subpart M—Grievances, Organization Determinations and Appeals

* * * * *

§ 422.562 General provisions.

(a) *Responsibilities of the M+C organization.* (1) An M+C organization, with respect to each M+C plan that it offers, must establish and maintain—

(i) A grievance procedure as described in § 422.564 for addressing issues that do not involve organization determinations;

(ii) A procedure for making timely organization determinations; and

(iii) Appeal procedures that meet the requirements of this subpart for issues that involve organization determinations; and

(2) An M+C organization must ensure that all enrollees receive written information about the—

(i) Grievance and appeal procedures that are available to them through the M+C organization; and

(ii) Complaint process available to the enrollee under the PRO process as set forth under section 1154(a)(14) of the Act.

(3) In accordance with subpart K of this part, if the M+C organization delegates any of its responsibilities under this subpart to another entity or individual through which the organization provides health care services, the M+C organization is ultimately responsible for ensuring that the entity or individual satisfies the relevant requirements of this subpart.

(b) *Rights of M+C enrollees.* In accordance with the provisions of this subpart, enrollees have the following rights:

(1) The right to have grievances between the enrollee and the M+C organization heard and resolved, as described in § 422.564.

(2) The right to a timely organization determination, as provided under § 422.566.

(3) The right to request an expedited organization determination, as provided under § 422.570.

(4) If dissatisfied with any part of an organization determination, the following appeal rights:

(i) The right to a reconsideration of the adverse organization determination by the M+C organization, as provided under § 422.578.

(ii) The right to request an expedited reconsideration, as provided under § 422.584.

(iii) If, as a result of a reconsideration, an M+C organization affirms, in whole or in part, its adverse organization determination, the right to an automatic reconsidered determination made by an independent, outside entity contracted by HCFA, as provided in § 422.592.

(iv) The right to an ALJ hearing if the amount in controversy is $100 or more, as provided in § 422.600.

(v) The right to request DAB review of the ALJ hearing decision, as provided in § 422.608.

(vi) The right to judicial review of the hearing decision if the amount in controversy is $1000 or more, as provided in § 422.612.

(c) *Limits on when this subpart applies.* (1) If an enrollee receives immediate PRO review (as provided

in § 422.622) of a determination of noncoverage of inpatient hospital care—

(i) The enrollee is not entitled to review of that issue by the M+C organization; and

(ii) The PRO review decision is subject only to the appeal procedures set forth in part 473 of this chapter.

(2) If an enrollee has no further liability to pay for services that were furnished by an M+C organization, a determination regarding these services is not subject to appeal.

(d) *When other regulations apply.* Unless this subpart provides otherwise, the regulations in 20 CFR, part 404, subparts J and R (covering, respectively, the administrative review and hearing process and representation of parties under title II of the Act), apply under this subpart to the extent they are appropriate.

§ 422.564 Grievance procedures.

(a) *General rules.* (1) Each M+C organization must provide meaningful procedures for timely hearing and resolution of grievances between enrollees and the organization or any other entity or individual through which the organization provides health care services under any M+C plan it offers.

(2) Grievance procedures must meet any guidelines established by HCFA.

(b) *Distinguished from organization determinations and appeals.* Grievance procedures are separate and distinct from organization determinations and appeal procedures, which address organization determinations.

(c) *Distinguished from the PRO complaint process.* Under section 1154(a)(14) of the Act, the PRO must

review beneficiaries' written complaints about the quality of services they have received under the Medicare program; this process is separate and distinct from the grievance procedures of the M+C organization.

§ 422.566 Organization determinations.

(a) *Responsibilities of the M+C organization.* Each M+C organization must have a procedure for making timely organization determinations (in accordance with the requirements of this subpart) regarding the benefits an enrollee is entitled to receive under an M+C plan, including basic benefits as described under § 422.100(c)(1) and mandatory and optional supplemental benefits as described under § 422.102, and the amount, if any, that the enrollee is required to pay for a health service. The M+C organization must have a standard procedure for making determinations, in accordance with § 422.568, and an expedited procedure for situations in which applying the standard procedure could seriously jeopardize the enrollee's life, health, or ability to regain maximum function, in accordance with §§ 422.570 and 422.572.

(b) *Actions that are organization determinations.* An organization determination is any determination made by an M+C organization with respect to any of the following:

(1) Payment for emergency services, post-stabilization care, or urgently needed services.

(2) Payment for any other health services furnished by a provider other than the M+C organization that the enrollee believes—

(i) Are covered under Medicare; or

(ii) If not covered under Medicare, should have been furnished, arranged for, or reimbursed by the M+C organization.

(3) The M+C organization's refusal to provide services that the enrollee believes should be furnished or arranged for by the M+C organization when the enrollee has not received the services outside the M+C organization.

(4) Discontinuation of a service, if the enrollee disagrees with the determination that the service is no longer medically necessary.

(c) *Who can request an organization determination.* Any of the parties listed in § 422.574 can request an organization determination, with the exception that only the parties listed in § 422.570(a) can request an expedited determination.

§ 422.568 Standard timeframes and notice requirements for organization determinations.

(a) *Timeframe for requests for service.* When a party has made a request for a service, the M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination. The M+C organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). The M+C organization must notify the enrollee of its determination as expeditiously as the

enrollee's health condition requires, but no later than upon expiration of the extension.

(b) *Timeframe for requests for payment.* The M+C organization must process requests for payment according to the "prompt payment" provisions set forth in § 422.520.

(c) *Written notification for denials.* If an M+C organization decides to deny service or payment in whole or in part, it must give the enrollee written notice of the determination.

(d) *Content of the notice.* The notice of any denial under paragraph (c) of this section must—

(1) State the specific reasons for the denial in understandable language;

(2) Inform the enrollee of his or her right to a reconsideration;

(3) Describe both the standard and expedited reconsideration processes, including the enrollee's right to and conditions for obtaining an expedited reconsideration for service requests, and the rest of the appeal process; and

(4) Comply with any other requirements specified by HCFA.

(e) *Effect of failure to provide timely notice.* If the M+C organization fails to provide the enrollee with timely notice of an organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed.

§ 422.570 Expediting certain organization determinations.

(a) *Request for expedited determination.* An enrollee or a physician (regardless of whether the physician is affiliated with the M+C organization) may request that an M+C organization expedite an organization determination involving the issues described in § 422.566(b)(3) and (b)(4). (This does not include requests for payment.)

(b) *How to make a request.* (1) To ask for an expedited determination, an enrollee or a physician must submit an oral or written request directly to the M+C organization or, if applicable, to the entity responsible for making the determination, as directed by the M+C organization.

(2) A physician may provide oral or written support for a request for an expedited determination.

(c) *How the M+C organization must process requests.* The M+C organization must establish and maintain the following procedures for processing requests for expedited determinations:

(1) Establish an efficient and convenient means for individuals to submit oral or written requests. The M+C organization must document all oral requests in writing and maintain the documentation in the case file.

(2) Promptly decide whether to expedite a determination, based on the following requirements:

(i) For a request made by an enrollee the M+C organization must provide an expedited determination if it determines that applying the standard timeframe for making a determination could seriously jeopardize

the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by a physician, the M+C organization must provide an expedited determination if the physician indicates that applying the standard timeframe for making a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial.* If an M+C organization denies a request for expedited determination, it must take the following actions:

(1) Automatically transfer a request to the standard timeframe and make the determination within the 14-day timeframe established in § 422.568 for a standard determination. The 14-day period begins with the day the M+C organization receives the request for expedited determination.

(2) Give the enrollee prompt oral notice of the denial and follow up, within 2 working days, with a written letter that—

(i) Explains that the M+C organization will process the request using the 14-day timeframe for standard determinations;

(ii) Informs the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision not to expedite; and

(iii) Provides instructions about the grievance process and its timeframes.

(e) *Action on accepted request for expedited determination.* If an M+C organization grants a request for expedited determination, it must make the determination and give notice in accordance with § 422.572.

(f) *Prohibition of punitive action.* An M+C organization may not take or threaten to take any punitive action against a physician acting on behalf or in support of an enrollee in requesting an expedited determination.

§ 422.572 Timeframes and notice requirements for expedited organization determinations.

(a) *Timeframe.* Except as provided in paragraph (b) of this section, an M+C organization that approves a request for expedited determination must make its determination and notify the enrollee (and the physician involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request.

(b) *Extensions.* The M+C organization may extend the 72-hour deadline by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). The M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(c) *Confirmation of oral notice.* If the M+C organization first notifies an enrollee of its expedited determination orally, it must mail written confirmation to the enrollee within 2 working days of the oral notification.

(d) *How information from noncontract providers affects timeframes for expedited determinations.* If an M+C organization must receive medical information

from noncontract providers, the 72-hour period begins when the organization receives that information. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information in order to receive timely payment.

(e) *Content of the notice of expedited determination.* (1) The notice of any expedited determination must state the specific reasons for the determination in understandable language.

(2) If the determination is not completely favorable to the enrollee, the notice must—

(i) Inform the enrollee of his or her right to a reconsideration;

(ii) Describe both the standard and expedited reconsideration processes, including the enrollee's right to request, and conditions for obtaining, an expedited reconsideration, and the rest of the appeal process; and

(iii) Comply with any other requirements specified by HCFA.

(f) *Effect of failure to provide a timely notice.* If the M+C organization fails to provide the enrollee with timely notice of an expedited organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed.

§ 422.574 Parties to the organization determination.

The parties to the organization determination are—

(a) The enrollee (including his or her authorized representative);

(b) An assignee of the enrollee (that is, a physician or other provider who has furnished a service to the

enrollee and formally agrees to waive any right to payment from the enrollee for that service);

(c) The legal representative of a deceased enrollee's estate; or

(d) Any other provider or entity (other than the M+C organization) determined to have an appealable interest in the proceeding.

§ 422.576 Effect of an organization determination.

The organization determination is binding on all parties unless it is reconsidered under §§ 422.578 through 422.596 or is reopened and revised under § 422.616.

§ 422.578 Right to a reconsideration.

Any party to an organization determination (including one that has been reopened and revised as described in § 422.616) may request that the determination be reconsidered under the procedures described in § 422.582, which address requests for a standard reconsideration. An enrollee or physician (acting on behalf of an enrollee) may request an expedited reconsideration as described in § 422.584.

§ 422.580 Reconsideration defined.

A reconsideration consists of a review of an adverse organization determination, the evidence and findings upon which it was based, and any other evidence the parties submit or the M+C organization or HCFA obtains.

§ 422.582 Request for a standard reconsideration.

(a) *Method and place for filing a request.* A party to an organization determination must ask for a reconsideration of the determination by filing a written request with—

(1) The M+C organization that made the organization determination;

(2) An SSA office; or

(3) In the case of a qualified railroad retirement beneficiary, an RRB office.

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, a party must file a request for a reconsideration within 60 calendar days from the date of the notice of the organization determination. If the SSA or RRB receives a request, it forwards the request to the M+C organization for its reconsideration. The timeframe within which the organization must conduct its review begins when it receives the request.

(c) *Extending the time for filing a request.*

(1) *General rule.* If a party shows good cause, the M+C organization may extend the timeframe for filing a request for reconsideration.

(2) *How to request an extension of timeframe.* If the 60-day period in which to file a request for a reconsideration has expired, a party to the organization determination may file a request for reconsideration with the M+C organization, SSA, or an RRB office. If SSA or RRB receives a request, it forwards the request to the M+C organization for its reconsideration. The request for reconsideration and to extend the timeframe must—

(i) Be in writing; and

(ii) State why the request for reconsideration was not filed on time.

(d) *Parties to the reconsideration.* The parties to the reconsideration are the parties to the organization determination, as described in § 422.574, and any other provider or entity (other than the M+C organization) whose rights with respect to the organization determination may be affected by the reconsideration, as determined by the entity that conducts the reconsideration.

(e) *Withdrawing a request.* The party who files a request for reconsideration may withdraw it by filing a written request for withdrawal at one of the places listed in paragraph (a) of this section.

§ 422.584 Expediting certain reconsiderations.

(a) *Who may request an expedited reconsideration.* An enrollee or a physician (regardless of whether he or she is affiliated with the M+C organization) may request that an M+C organization expedite a reconsideration of a determination that involves the issues described in § 422.566(b)(3) and (b)(4). (This does not include requests for payment.) A physician that requests an expedited reconsideration must be acting on behalf of the enrollee as an authorized representative.

(b) *How to make a request.* (1) To ask for an expedited reconsideration, an enrollee or a physician acting on behalf of an enrollee must submit an oral or written request directly to the M+C organization or, if applicable, to the entity responsible for making the reconsideration, as directed by the M+C organization.

(2) A physician may provide oral or written support for a request for an expedited reconsideration.

(c) *How the M+C organization must process requests.* The M+C organization must establish and main-

tain the following procedures for processing requests for expedited reconsiderations:

(1) *Handling of requests.* The M+C organization must establish an efficient and convenient means for individuals to submit oral or written requests, document all oral requests in writing, and maintain the documentation in the case file.

(2) *Prompt decision.* Promptly decide on whether to expedite the reconsideration or follow the timeframe for standard reconsideration based on the following requirements:

(i) For a request made by an enrollee, the M+C organization must provide an expedited reconsideration if it determines that applying the standard timeframe for reconsidering a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by a physician, the M+C organization must provide an expedited reconsideration if the physician indicates that applying the standard timeframe for conducting a reconsideration could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial.* If an M+C organization denies a request for expedited reconsideration, it must take the following actions:

(1) Automatically transfer a request to the standard timeframe and make the determination within the 30-day timeframe established in § 422.590(a). The 30-day period begins the day the M+C organization receives the request for expedited reconsideration.

(2) Give the enrollee prompt oral notice, and follow up, within 2 working days, with a written letter that—

(i) Explains that the M+C organization will process the enrollee's request using the 30-day timeframe for standard reconsiderations;

(ii) Informs the enrollee of the right to file a grievance if he or she disagrees with the organization's decision not to expedite; and

(iii) Provides instructions about the grievance process and its timeframes.

(e) *Action following acceptance of a request.* If an M+C organization grants a request for expedited reconsideration, it must conduct the reconsideration and give notice in accordance with § 422.590(d).

(f) *Prohibition of punitive action.* An M+C organization may not take or threaten to take any punitive action against a physician acting on behalf or in support of an enrollee in requesting an expedited reconsideration.

§ 422.586 Opportunity to submit evidence.

The M+C organization must provide the parties to the reconsideration with a reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing. In the case of an expedited reconsideration, the opportunity to present evidence is limited by the short timeframe for making a decision. Therefore, the M+C organization must inform the parties of the conditions for submitting the evidence.

§ 422.590 Timeframes and responsibility for reconsiderations.

(a) *Standard reconsideration: Request for services.*

(1) If the M+C organization makes a reconsidered determination that is completely favorable to the enrollee, the M+C organization must issue the determination (and effectuate it in accordance with § 422.618(a)) as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration. The M+C organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). For extensions, the M+C organization must issue and effectuate its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(2) If the M+C organization makes a reconsidered determination that affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted by HCFA as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration (or no later than the expiration of an extension described in paragraph (a)(1) of this section). The organization must make reasonable and diligent efforts to assist in gather-

ing and forwarding information to the independent entity.

(b) *Standard reconsideration: Request for payment.* (1) If the M+C organization makes a reconsidered determination that is completely favorable to the enrollee, the M+C organization must issue its reconsidered determination to the enrollee (and effectuate it in accordance with § 422.618(a)) no later than 60 calendar days from the date it receives the request for a standard reconsideration.

(2) If the M+C organization affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted by HCFA no later than 60 calendar days from the date it receives the request for a standard reconsideration. The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(c) *Effect of failure to meet timeframe for standard reconsideration.* If the M+C organization fails to provide the enrollee with a reconsidered determination within the timeframes specified in paragraph (a) or paragraph (b) of this section, this failure constitutes an affirmation of its adverse organization determination, and the M+C organization must submit the file to the independent entity in the same manner as described under paragraphs (a)(2) and (b)(2) of this section.

(d) *Expedited reconsideration—(1) Timeframe.* Except as provided in paragraph (d)(2) of this section, an M+C organization that approves a request for expedited reconsideration must complete its reconsideration and give the enrollee (and the physician involved, as

appropriate) notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request.

(2) *Extensions.* The M+C organization may extend the 72-hour deadline by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). The M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires but no later than upon expiration of the extension.

(3) *Confirmation of oral notice.* If the M+C organization first notifies an enrollee orally of a completely favorable expedited reconsideration, it must mail written confirmation to the enrollee within 2 working days.

(4) *How information from noncontract providers affects timeframes for expedited reconsiderations.* If the M+C organization must receive medical information from noncontract providers, the 72-hour period begins when the organization receives the information. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information in order to receive timely payment.

(5) *Affirmation of an adverse expedited organization determination.* If, as a result of its reconsideration, the M+C organization affirms, in whole or in part, its adverse expedited organization determination, the M+C organization must submit a written explanation and the case file to the independent entity contracted by HCFA as expeditiously as the enrollee's health

condition requires, but not later than within 24 hours of its affirmation. The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(e) *Notification of enrollee.* If the M+C organization refers the matter to the independent entity as described under this section, it must concurrently notify the enrollee of that action.

(f) *Failure to meet timeframe for expedited reconsideration.* If the M+C organization fails to provide the enrollee with the results of its reconsideration within the timeframe described in paragraph (d) of this section, this failure constitutes an adverse reconsidered determination, and the M+C organization must submit the file to the independent entity within 24 hours of expiration of the timeframe set forth in paragraph (d) of this section.

(g) *Who must reconsider an adverse organization determination.* (1) A person or persons who were not involved in making the organization determination must conduct the reconsideration.

(2) When the issue is the M+C organization's denial of coverage based on a lack of medical necessity, the reconsidered determination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue.

§ 422.592 Reconsideration by an independent entity.

(a) When the M+C organization affirms, in whole or in part, its adverse organization determination, the issues that remain in dispute must be reviewed and resolved by an independent, outside entity that contracts with HCFA.

(b) The independent outside entity must conduct the review as expeditiously as the enrollee's health condition requires but must not exceed the deadlines specified in the contract.

(c) When the independent entity conducts a reconsideration, the parties to the reconsideration are the same parties listed in § 422.582(d) who qualified during the M+C organization's reconsideration, with the addition of the M+C organization.

§ 422.594 Notice of reconsidered determination by the independent entity.

(a) *Responsibility for the notice.* When the independent entity makes the reconsidered determination, it is responsible for mailing a notice of its reconsidered determination to the parties and for sending a copy to HCFA.

(b) *Content of the notice.* The notice must—

(1) State the specific reasons for the entity's decisions;

(2) If the reconsidered determination is adverse (that is, does not completely reverse the M+C organization's adverse organization determination), inform the parties of their right to an ALJ hearing if the amount in controversy is $100 or more;

(3) Describe the procedures that a party must follow to obtain an ALJ hearing; and

(4) Comply with any other requirements specified by HCFA.

§ 422.596 Effect of a reconsidered determination.

A reconsidered determination is final and binding on all parties unless a party files a request for a hearing under the provisions of § 422.602, or unless the reconsidered determination is revised under § 422.616.

§ 422.600 Right to a hearing.

(a) If the amount remaining in controversy is $100 or more, any party to the reconsideration (except the M+C organization) who is dissatisfied with the reconsidered determination has a right to a hearing before an ALJ. The M+C organization does not have the right to request a hearing before an ALJ.

(b) The amount remaining in controversy, which can include any combination of Part A and Part B services, is computed in accordance with § 405.740 of this chapter for Part A services and § 405.817 of this chapter for Part B services.

(c) If the basis for the appeal is the M+C organization's refusal to provide services, HCFA uses the projected value of those services to compute the amount remaining in controversy.

§ 422.602 Request for an ALJ hearing.

(a) *How and where to file a request.* A party must file a written request for a hearing at one of the places listed in § 422.582(a) or with the independent, outside entity. The organizations listed in § 422.582(a) forward the request to the independent, outside entity, which is

responsible for transferring the case to the appropriate ALJ hearing office.

(b) *When to file a request.* Except when an ALJ extends the timeframe as provided in 20 CFR 404.933(c), a party must file a request for a hearing within 60 days of the date of the notice of a reconsidered determination.

(c) *Parties to a hearing.* The parties to a hearing are the parties to the reconsideration, the M+C organization, and any other person or entity whose rights with respect to the reconsideration may be affected by the hearing, as determined by the ALJ.

(d) *When the amount in controversy is less than $100.* (1) If a request for a hearing clearly shows that the amount in controversy is less than $100, the ALJ dismisses the request.

(2) If, after a hearing is initiated, the ALJ finds that the amount in controversy is less than $100, he or she discontinues the hearing and does not rule on the substantive issues raised in the appeal.

§ 422.608 Departmental Appeals Board (DAB) review.

Any party to the hearing, including the M+C organization, who is dissatisfied with the ALJ hearing decision, may request that the DAB review the ALJ's decision or dismissal. Regulations located at 20 CFR 404.967 through 404.984 regarding SSA Appeals Council Review apply to DAB review for matters addressed by this subpart.

§ 422.612 Judicial review.

(a) *Review of ALJ's decision.* Any party, including the M+C organization, may request judicial review

(upon notifying the other parties) of an ALJ's decision if—

(1) The DAB denied the party's request for review; and

(2) The amount in controversy is $1,000 or more.

(b) *Review of DAB decision.* Any party, including the M+C organization, may request judicial review (upon notifying the other parties) of the DAB decision if—

(1) It is the final decision of HCFA; and

(2) The amount in controversy is $1,000 or more.

(c) *How to request judicial review.* A party must file a civil action in a district court of the United States in accordance with section 205(g) of the Act (see 20 CFR 422.210 for a description of the procedures to follow in requesting judicial review).

§ 422.616 Reopening and revising determinations and decisions.

(a) An organization or reconsidered determination made by an M+C organization, a reconsidered determination made by the independent entity described in § 422.592, or the decision of an ALJ or the DAB that is otherwise final and binding may be reopened and revised by the entity that made the determination or decision, under the rules in § 405.750 of this chapter.

(b) Reopening may be at the instigation of any party.

(c) The filing of a request for reopening does not relieve the M+C organization of its obligation to make payment or provide services as specified in § 422.618.

(d) Once an entity issues a revised determination or decision, any party may file an appeal.

§ 422.618 How an M+C organization must effectuate reconsidered determinations or decisions.

(a) *Reversals by the M+C organization*—(1) *Requests for service.* If, on reconsideration of a request for service, the M+C organization completely reverses its organization determination, the organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days after the date the M+C organization receives the request for reconsideration (or no later than upon expiration of an extension described in § 422.590(a)(1)).

(2) *Requests for payment.* If, on reconsideration of a request for payment, the M+C organization completely reverses its organization determination, the organization must pay for the service no later than 60 calendar days after the date the M+C organization receives the request for reconsideration.

(b) *Reversals other than by the M+C organization.* If the M+C organization's organization determination is reversed in whole or in part by the independent outside entity or at a higher level of appeal, the M+C organization must pay for, authorize, or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 calendar days from the date it receives notice reversing the organization determination. The M+C organization must also inform the independent, outside entity that the organization has effectuated the decision.

§ 422.620 How M+C organizations must notify enrollees of noncoverage of inpatient hospital care.

(a) *Enrollee's entitlement.* Where an M+C organization has authorized coverage of the inpatient admission of an enrollee, either directly or by delegation (or the admission constitutes emergency or urgently needed care, as described in §§ 422.2 and 422.112(b)), the enrollee remains entitled to inpatient hospital care until he or she receives notice of noncoverage of that care.

(b) *Physician concurrence required.* Before the M+C organization gives notice of noncoverage as described in paragraph (c) of this section, the physician who is responsible for the enrollee's hospital care must concur.

(c) *Notice to the enrollee.* The M+C organization must give the enrollee written notice that includes the following:

(1) The reason why inpatient hospital care is no longer needed.

(2) The effective date of the enrollee's liability for continued inpatient care.

(3) The enrollee's appeal rights.

(4) Comply with any other requirements specified by HCFA.

(d) *Physician concurrence when a hospital determines if care is necessary.* If the M+C organization allows the hospital to determine whether inpatient care is necessary, the hospital obtains the concurrence of the contracting physician responsible for the enrollee's hospital care or of another physician as authorized by the M+C organization, and notifies the enrollee, follow-

ing the procedures set forth in § 412.42(c)(3) of this chapter.

§ 422.622 Requesting immediate PRO review of noncoverage of inpatient hospital care.

(a) *Enrollee's right to review or reconsideration.* (1) An enrollee who wishes to appeal a determination by an M+C organization or hospital that inpatient care is no longer necessary must request immediate PRO review of the determination in accordance with paragraph (b) of this section. An enrollee who requests immediate PRO review may remain in the hospital with no additional financial liability as specified in paragraph (c) of this section.

(2) An enrollee who fails to request immediate PRO review in accordance with the procedures in paragraph (b) of this section may request expedited reconsideration by the M+C organization as described in § 422.584, but the financial liability rules of paragraph (c) of this section do not apply.

(b) *Procedures enrollee must follow.* For the immediate PRO review process, the following rules apply:

(1) The enrollee must submit the request for immediate review—

(i) To the PRO that has an agreement with the hospital under § 466.78 of this chapter;

(ii) In writing or by telephone; and

(iii) By noon of the first working day after he or she receives written notice that the M+C organization or hospital has determined that the hospital stay is no longer necessary.

(2) On the date it receives the enrollee's request, the PRO must notify the M+C organization that the enrollee has filed a request for immediate review.

(3) The M+C organization must supply any information that the PRO requires to conduct its review and must make it available, by phone or in writing, by the close of business of the first full working day immediately following the day the enrollee submits the request for review.

(4) In response to a request from the M+C organization, the hospital must submit medical records and other pertinent information to the PRO by close of business of the first full working day immediately following the day the organization makes its request.

(5) The PRO must solicit the views of the enrollee who requested the immediate PRO review.

(6) The PRO must make a determination and notify the enrollee, the hospital, and the M+C organization by close of business of the first working day after it receives all necessary information from the hospital, or the organization, or both.

(c) *Liability for hospital costs*—(1) *When the M+C organization determines that hospital services are not, or are no longer, covered.* (i) Except as provided in paragraph (c)(1)(ii) of this section, if the M+C organization authorized coverage of the inpatient admission directly or by delegation (or the admission constitutes emergency or urgently needed care, as described in §§ 422.2 and 422.112(b)), the organization continues to be financially responsible for the costs of the hospital stay when a timely appeal is filed under paragraph (a)(1) of this section until noon of the calendar day following the day the PRO notifies the enrollee of its

review determination. If coverage of the hospital admission was never approved by the M+C organization (or the admission does not constitute emergency or urgently needed care, as described in §§ 422.2 and 422.112(b)), the M+C organization is liable for the hospital costs only if it is determined on appeal that the hospital stay should have been covered under the M+C plan.

(ii) The hospital may not charge the M+C organization (or the enrollee) if—

(A) It was the hospital (acting on behalf of the enrollee) that filed the request for immediate PRO review; and

(B) The PRO upholds the noncoverage determination made by the M+C organization.

(2) *When the hospital determines that hospital services are no longer required.* If the hospital determines that inpatient hospital services are no longer necessary, and the enrollee could not reasonably be expected to know that the services would not be covered, the hospital may not charge the enrollee for inpatient services received before noon of the calendar day following the day the PRO notifies the enrollee of its review determination.

APPENDIX I

42 C.F.R. 417.608-417.634 (1996), superseded by 63 Fed. Reg. 34,968 (1998), provided as follows:

§ 417.608 Notice of adverse organization determinations.

(a) if an HMO or CMP makes an organization determination that is partially or fully adverse to the enrollee, it must notify the enrollee of the determination within 60 days of receiving the enrollee's request for payment for services.

(b) The notice must—

(1) State the specific reasons for the determination; and

(2) Inform the enrollee of his or her right to reconsideration.

(c) The failure to provide the enrollee with timely notification of an adverse organization determination constitutes an adverse organization determination and may be appealed.

[50 FR 1346, Jan. 10, 1985, as amended at 59 FR 59942, Nov. 21, 1994]

§ 417.610 Parties to the organization determination.

The parties to the organization determination are—

(a) The enrollee;

(b) An assignee of the enrollee (that is, a physician or other supplier who has provided a service to the enrollee and formally agrees to waive any right to payment from the enrolee for that service);

(c) The legal representative of a deceased enrollee's estate; or

(d) Any other entity determined to have an appealable interest in the proceeding.

[50 FR 1346, Jan. 10, 1985, as amended at 59 FR 59942, Nov. 21, 1994]

§ 417.612 Effect of organization determination.

The organization determination is final and binding on all parties unless it is reconsidered in accordance with §§ 417.614 through 417.626, or revised in accordance with § 417.638.

[50 FR 1346, Jan. 10, 1985, as amended at 59 FR 59941, Nov. 21, 1994]

§ 417.614 Right to reconsideration

Any party who is dissatisfied with an organization determination or with one that has been reopened and revised may request reconsideration of the determination in accordance with the procedures of § 417.616.

[59 FR 59942, Nov. 21, 1994]

§ 417.616 Request for reconsideration

(a) *Method and place for filing a request.* A request for reconsideration must be made in writing and filed with—(1) The HMO or CMP that made the organization determination;

(2) An SSA office; or

(3) In the case of a qualified railroad retirement beneficiary, an RRB office.

(b) *Time for filing a request.* Except as provided in paragraph (c) of this section, the request for reconsideration must be filed within 60 days from the date of the notice of the organization determination.

(c) *Extension of time to file a request.* (1) *Rule.* If good cause is shown, the HMO or CMP that made the organization determination may extend the time for filing the request for reconsideration.

(2) *Method of requesting an extension.* If the time limit in paragraph (b) of this section has expired, a party to the organization determination may file a request for reconsideration with the HMO or CMP, HCFA, SSA, or, in the case of qualified railroad retirement beneficiary, the RRB office. The request to extend the time limit must—

(i) Be in writing; and

(ii) State why the request for reconsideration was not filed timely.

(d) *Parties to the reconsideration.* The parties to the reconsideration are the parties to the initial determination as described in 417.610, and any other person or entity whose rights with respect to the initial determination may be affected by the reconsideration, as determined by the entity that conducts the reconsideration.

(e) *Withdrawal of request.* A request for reconsideration may be withdrawn by the party who filed the request. The request for withdrawal must be filed at one of the places specified in paragraph (c)(2) of this section.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 59 FR 59942, Nov. 21, 1994]

§ 417.618 Opportunity to submit evidence.

The HMO or CMP must provide the parties to the reconsideration reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38083, July 15, 1993; 59 FR 59942, Nov. 21, 1994]

§ 417.620 Responsibility for reconsiderations; time limits.

(a) If the HMO or CMP can make a reconsidered determination that is completely favorable to the enrollee, the HMO or CMP issues the reconsideration determination.

(b) If the HMO or CMP recommends partial or complete affirmation of its adverse determination, the HMO or CMP must prepare a written explanation and send the entire case to HFCA. HCFA makes the reconsidered datermination.

(c) The HMO or CMP must issue the reconsidered determinations to the enrollee, or submit the explanation and file to HCFA, within 60 calendar days from the date of receipt of the request for reconsideration.

(d) For good cause shown, HCFA may allow expeditions to the time limit set forth in paragraph (c) of this section.

(e) Failure by the HMO or CMP to provide the enrollee with a reconsidered determination within the 60-day limit described in paragraph (c) of this section or to obtain a good cause extension described in paragraph (d) of this section constitutes an adverse determination, and the HMO or CMP must submit the file to HCFA.

(f) If the HMO or CMP refers the matter to HCFA, it must concurrently notify the beneficiary of that action.

[59 FR 59942, Nov. 21, 1994]

§ 417.622 Reconsidered determination

A reconsidered determination is a new determination that—

(a) Is based on a review of the organization determination, the evidence and findings upon which it was based, and any other evidence submitted by the parties or obtained by HCFA or the HMO or CMP; and

(b) Is made by a person or persons who were not involved in making the organization determination.

[50 FR 1346, Jan. 10, 1985, as amended at 59 FR 59941, 59942, Nov. 21, 1994]

§ 417.624 Notice of reconsidered determination.

(a) *Responsibility for notice.* The entity that makes the reconsidered determination is responsible for mailing notice to the parties and, if that entity is not HCFA, for sending a copy to HCFA.

(b) *Content of notice.* The notice must—

(1) State the specific reasons for the reconsidered determination;

(2) Inform the party of his or her right to a hearing if the amount in controversy is $100 or more; and

(3) Describe the procedures that the party must follow to obtain a hearing.

[50 FR 1346, Jan. 10, 1985]

§ 417.630 Right to a hearing.

If the amount remaining in controversy is $100 or more, any party to the reconsideration who is dissatisfied with the reconsidered determination has a right to a hearing. (The amount remaining in controversy, which can include any combination of Part A and Part B services, is computed in accordance with § 405.740 of this chapter for Part A services and § 405.820(b) of this chapter for Part B services. If the basis for the appeal is the refusal of services, the projected value of those services is used in computing the amount remaining in controversy.)

[59 FR 59942, Nov. 21, 1994]

§ 417.632 Request for hearing.

(a) *Method and place for filing a request.* A request for a hearing must be made in writing and filed at one of the places specified in § 417.616(a).

(b) *Time for filing a request.* Except when the time is extended by a presiding officer as provided in 20 CFR 404.933(c), a request for a hearing must be filed within 60 days of the date of the notice of reconsidered determination.

(c) *Parties to a hearing.* (1) The parties to a hearing must be the parties to the reconsideration and any other person or entity whose rights with respect to the reconsideration may be affected by the hearing, as determined by the ALJ.

(2) The HMO or CMP must be made a party to the hearing but does not have a right to request a hearing.

(d) *ALJ action when the amount in controversy is less than $100.* (1) If the request plainly shows that the amount in controversy is less than $100, the ALJ dismisses the request.

(2) If, after a hearing is initiated, the ALJ finds that the amount in controversy is less than $100, he or she discontinues the hearing and does not rule on the substantive issues raised in the appeal.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 60 FR 46234, Sept. 6, 1995]

§ 417.623 Departmental Appeals Board review.

Any party to the hearing, including the HMO or CMP, who is dissatisfied with the hearing decision, may request the Departmental Appeals Board to review the ALJ's decision or dismissal. Provisions regarding Departmental Appeals Board review are contained in 20 CFR 404.967 through 404.983.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985; 58 FR 38083, July 15, 1993, as amended at 61 FR 32348, June 24, 1996]

§ 417.636 Court review.

(a) *Review of ALJ's decision.* A party or the HMO or CMP may request judicial review of an ALJ's decision if—

(1) The Departmental Appeals Board denied the party's or the HMO's or CMP's request for review; and

(2) The amount in controversy is $1,000 or more.

(b) *Review of Departmental Appeals Board decision.* A party or the HMO or CMP may request judicial review of the Departmental Appeals Board decision if—

(1) It is the final decision of HCFA; and

(2) The amount in controversy is $1,000 or more.

(c) *Request for review.* The civil action must be filed in a district court of the United States in accordance with section 205(g) of the Act (see 20 CFR 422.210 for a description of the procedures to follow in requesting judicial review).

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38083, July 15, 1993; 61 FR 32348, June 24, 1996]

§ 417.638 Reopening determinations and decisions

An organization, reconsidered, or revised determination made by an HMO, CMP, or HCFA, or a decision or revised decision of an ALJ or the Depart-

mental Appeals Board, may be reopened in accordance with the provisions of § 405.750 of this chapter.

[59 FR 59942, Nov. 21, 1994, as amended at 61 FR 32348, June 24, 1996]

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No. 98-1284

IN THE

Supreme Court of the United States

October Term, 1998

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES,

Petitioner,

v.

GREGORIA GRIJALVA, *et al.*,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF *AMICI CURIAE* HEALTH INSURANCE ASSOCIATION OF AMERICA AND BLUE CROSS AND BLUE SHIELD ASSOCIATION IN SUPPORT OF PETITIONER

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BRIEF OF *AMICI CURIAE* HEALTH INSURANCE ASSOCIATION OF AMERICA AND BLUE CROSS AND BLUE SHIELD ASSOCIATION IN SUPPORT OF PETITIONER

INTEREST OF AMICI CURIAE

The Health Insurance Association of America ("HIAA"), based in Washington, D.C.,[1] represents approximately 250 member companies that include health maintenance, preferred provider and other managed care organizations. Together, HIAA members provide medical expense and supplemental

[1] No party or its counsel has authored any part of this brief. No person or entity other than the Health Insurance Association of America and the Blue Cross and Blue Shield Association and their counsel has made a monetary contribution to the preparation or submission of this brief.

insurance, as well as long-term care insurance and disability income protection, to more than 110 million Americans. Managed care organizations owned and operated by HIAA member companies serve millions of Medicare beneficiaries throughout the United States.

The Blue Cross and Blue Shield Association ("BCBSA"), based in Chicago, Illinois, is a not-for-profit association representing the interests of fifty-two independent, locally operated Blue Cross and Blue Shield Plans, with a collective enrollment of more than seventy-one million subscribers. The majority of the member Plans operate Medicare managed care health programs serving more than one million beneficiaries nationwide. Together, the Plans also serve over fifteen percent of the total Medicaid managed care population.

Both HIAA and BCBSA (collectively "the Associations") believe that the Medicare managed care program is an essential component of the federal government's effort to ensure Medicare's financial survival and to meet the health care needs of an aging population. Accordingly, they are committed to promoting laws and policies that encourage successful Medicare managed care contracting. In this context, they develop and advocate policies to improve the health care system's quality, affordability, accessibility, efficiency and responsiveness. All of these issues are directly affected by the decisions below.

The Associations' members also have a direct and significant stake in the outcome of this case. Their managed care organizations will bear the brunt of the injunction entered by the district court and affirmed by the Ninth Circuit. If the Secretary of Health and Human Services ("the Secretary") is forced to implement the detailed procedural requirements of the injunction, managed care organizations will be forced to shift limited financial resources away from funding the provision of supplemental benefits for beneficiaries and allocate them instead to paperwork and administrative functions. Ultimately, the injunction would make it more

difficult for managed care organizations to participate in the Medicare+Choice program recently enacted by Congress as part of the Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251, in its continuing efforts to ensure the viability of the Medicare program.

Counsel for the parties have consented to the filing of this *amicus* brief. Their letters of consent have been filed with the Clerk.

REASONS FOR GRANTING THE WRIT

This case presents issues of great importance to the future of Medicare. As medical costs have increased and the population has aged,[2] Congress and the Secretary have increasingly relied on private sector health maintenance organizations and similar managed care entities (collectively, "HMOs") to provide Medicare beneficiaries high quality medical care in an efficient and cost-effective manner. The evolving legislative and regulatory framework, reflected most recently in the Medicare+Choice program, requires accommodation of numerous complex and often conflicting medical, economic and social issues. Policy choices are difficult, trade-offs are necessary and change is constant. Congress and the Secretary continue to struggle to strike the appropriate balance between regulatory protections and efficient, cost-effective delivery of health care services.

Yet at a time when innovation and flexibility are crucial, the Ninth Circuit has stepped in and placed the Secretary and the HMOs that she regulates in a constitutional straitjacket.

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[2] The Health Care Finance Administration ("HCFA") projects that national health expenditures will double from $1.1 trillion in 1996 to $2.1 trillion in 2007. *See The Next Ten Years of Health Spending: What Does the Future Hold?*, HEALTH AFF., Sept.-Oct. 1998. According to the Census Bureau, by 2025, the population age 65 and older will nearly double from about 34 million today (12.7% of the total population) to 62 million (18.5%). BUREAU OF THE CENSUS, U.S. DEP'T OF COMMERCE, STATISTICAL ABSTRACT OF THE UNITED STATES 1998, at 25.

The court of appeals affirmed a nationwide injunction requiring the Secretary to impose numerous specific and stringent requirements governing the manner in which HMOs may deny – or even alter – medical treatment to Medicare beneficiaries who have chosen to enroll in managed care programs. This decision, as a practical matter, takes the ability to regulate treatment decisions by private Medicare HMO contractors away from the Congressionally designated agency with expertise in the management and delivery of health care services and turns it over to a single district court that did not even hear medical testimony to clarify the terms of its injunction. Pet. App. 68a.

The Ninth Circuit endorsed this judicial intrusion into HMO Medicare regulation by affirming two clearly erroneous legal determinations made by the district court. First, the court below concluded that because the federal government extensively regulates Medicare HMO contractors, the decisions of those private health care providers as to whether medical treatment for their patients is appropriate and necessary constitute "federal action," subjecting the HMOs to constitutional requirements of due process. Pet. App. 8a-12a. Second, the court concluded that the applicable federal regulations (which have since been superseded) did not give the nationwide class of Medicare beneficiaries who voluntarily enrolled in HMOs the "process" that was "due" under the circumstances. Pet. App. 12a-18a.

This Court should grant the Secretary's petition, summarily reverse the court below and remand with instructions to vacate the injunction in light of *American Manufacturers Mutual Insurance Co. v. Sullivan*, No. 97-2000 (U.S. Mar. 3, 1999). The Court's holding in *Sullivan* that medical payment decisions made by private workers' compensation insurers do not constitute "state action" applies with equal force to the medical treatment decisions made by private Medicare HMO contractors that were at issue in the case below. The Ninth Circuit here, like the Third Circuit in *Sullivan*, confused government regulation with government

action. In this respect, the Ninth Circuit's decision is fundamentally inconsistent not only with *Sullivan* but with this Court's prior holding in *Blum v. Yaretsky*, 457 U.S. 991 (1982).

The Ninth Circuit's due process analysis also warrants summary reversal. To the extent that the court below assumed that Medicare beneficiaries have a constitutionally protected property interest in obtaining particular medical treatment, its decision directly conflicts with *Sullivan*. Slip op. at 17-20. In any event, the court's application of the balancing test mandated by *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976), is fatally flawed. The court essentially ignored the third factor of that test: "the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirements would entail." *Id.* As a result, the Ninth Circuit's decision substantially undermines the strong government interest in maintaining a financially and medically sound Medicare program through the use of private sector managed care organizations.[3]

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[3] The Secretary's petition suggests that the implementation of the Medicare+Choice program renders the decision below moot, and that therefore the Court should vacate and remand on that ground so that the lower courts can consider the constitutionality of the new program. Pet. at 20-25. The Ninth Circuit, however, was fully aware that the Secretary had implemented new regulations, yet brushed that fact aside when it affirmed the injunction. Pet. App. 20a. Moreover, the risk-sharing contract program established under 42 U.S.C. § 1395mm (1994) is structurally similar to the new Medicare+Choice program, and the private HMO contract option is included in both programs. To the extent that the Secretary's new regulations do not comport precisely with the requirements of the injunction (e.g., by allowing more than five days for an HMO to respond to non-urgent requests for treatment), they remain subject to constitutional challenge by the respondents. Thus, the Medicare+Choice program presents essentially the same questions of government action and due process that were considered in this case. *See Northeastern Fla. Chapter of Associated Gen. Contractors of Am. v. City of Jacksonville*, 508 U.S. 656, 662 (1993) (new ordinance did not make appeal moot because it disadvantaged plaintiffs "in the same fundamental way" albeit "to a lesser degree"); *City of Mesquite v. Aladdin's Castle*,

I. THE NINTH CIRCUIT'S "FEDERAL ACTION" HOLDING CONFLICTS WITH *SULLIVAN* AND *BLUM V. YARETSKY*

The Ninth Circuit's constitutionalization of Medicare HMO administrative procedures was premised on its determination that every decision by a private HMO to deny, terminate or reduce a medical service requested by a Medicare enrollee constitutes "federal action." Pet. App. 9a-12a.[4] The court based that determination on the facts that "[t]he Secretary extensively regulates the provision of Medicare services by HMOs," pays HMOs for enrolled Medicare beneficiaries and establishes the "legal framework . . . within which HMOs make adverse determinations, issue notices, and guarantee appeal rights." Pet. App. 10a. While acknowledging that none of these factors alone would be sufficient to establish federal action, the court held that "[t]ogether they show federal action." *Id.*

This conclusion is directly contrary to *Sullivan*. Slip op. at 10. The Court there made clear that extensive government regulation of private conduct does not make the conduct

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Inc., 455 U.S. 283, 289 (1982)("[A] defendant's voluntary cessation of a challenged practice does not deprive a federal court of its power to determine the legality of the practice."). Vacating and remanding on grounds of mootness would not address the lower courts' fundamentally erroneous legal rulings on those issues, which could be repeated on remand. Accordingly, the Associations submit that this case is ripe for reversal on the merits, whether summarily in light of the Court's decisions in *Sullivan*, *Blum* and *Mathews*, or after full plenary review.

[4] The injunction upheld by the Ninth Circuit requires written notice to be provided not only for denial or termination of medical treatment, but also whenever an HMO orders a "reduction" in services. Pet. App. 60a. This means that decisions, for example, to reduce the dosage or frequency of medications, or to taper off the frequency of visits by a home health care nurse to change postoperative dressings, would be deemed "government action" subject to the due process requirements imposed by the district court. *See* Second Declaration of Bruce M. Fried (then-Director of HCFA's Office of Managed Care) in Support of Defendant's Motion for Stay ("2d Fried Decl.") ¶ 6. (The 2d Fried Decl. is referred to at Pet. App. 66a-67a.)

"state action"; rather, the conduct must be coerced or significantly encouraged by the government. *Id.*; *Blum*, 457 U.S. at 1004. None of the factors relied upon by the court of appeals, taken separately or together, establishes that the government either compels or encourages the decisions made by HMOs in determining whether to deny, terminate or reduce treatments requested by their Medicare enrollees. Rather, such decisions are made entirely "by private parties according to professional standards that are not established by the [government]." *Blum*, 457 U.S. at 1008. These decisions are no more government action than were the decisions of the private insurers in *Sullivan* to suspend payment for medical treatment.

In finding "federal action," the Ninth Circuit failed to recognize the crucial distinction between the Medicare fee-for-service program and the private managed care program involved in this case. In the former, private contractors act expressly as agents of the government to make decisions whether particular medical treatments are covered and therefore reimbursable. In the private alternative managed care program, the Secretary pays HMOs a flat fee for each Medicare enrollee. The HMOs and the doctors with whom they contract are then free to determine whether a particular covered service is medically necessary for an enrollee. Enrollees are free to leave and return to the traditional fee-for-service Medicare program.[5] The fact that the Secretary

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[5] It is clear that Congress intended Medicare HMO contractors to act as private entities serving Medicare beneficiaries, not as agents of the government. In establishing the Medicare managed care option in 1972, Congress intended to make Medicare relate to HMOs "in a way that conforms more nearly to their usual way of doing business," providing, "in the case of medicare beneficiaries, the same kind of financial incentives that health maintenance organizations have with respect to their other enrollees." H.R. Rep. No. 92-231 (1972), *reprinted in* 1972 U.S.C.C.A.N. 4989, 5076. *See also* 50 Fed. Reg. 1314 (1985) (1972 amendments were made to "conform more closely to the usual way in which HMOs operate" and thereby give them their usual incentive "to provide a continuum of services, to keep costs low, and to control utilization of services").

regulates the manner in which such services are provided by HMOs and requires an administrative appeals system for Medicare enrollees denied services does not convert this private activity into government action. *Sullivan*, slip op. at 12.

In *Sullivan*, the Court compared the private insurers' decisions to withhold payment for treatment to the decisions "to transfer Medicaid patients to a lower level of care" that the Court held in *Blum* to be private not state action. Slip op. at 11. The HMO decisions challenged in this case are virtually identical to those at issue in *Blum*. The Ninth Circuit distinguished *Blum* based on its finding that HMO decisions denying requests for medical treatment are not "merely medical judgments" but are "more accurately described as coverage decisions." Pet. App. 11a. That conclusion is simply wrong. HMO's make coverage decisions based upon medical information, not regulatory interpretation. Here, as the district court indicated, the private actions complained of were "primarily denials for Skilled Nursing Facility (SNF) care." Pet. App. 48a. Applicable regulations make clear that coverage for care in a SNF is provided only when it is "required" or "medically necessary." Pet. App. 48a. Thus, the determination whether such a service is "covered" is a contractual decision, based upon medical standards that are neither established nor authorized by the government. *Blum* is dispositive of this case.

The court of appeals relied on *Burton v. Wilmington Parking Authority*, 365 U.S. 715 (1961), to support its conclusion that government action exists because there is a "symbiotic relationship with a high degree of interdependence" between the Secretary and Medicare HMO contractors. Pet. App. 9a; *see also id.* at 11a-12a. In this respect, the Ninth Circuit committed the same error for which this Court has just reversed the Third Circuit in *Sullivan*: the court below "seems to have figuratively thrown up its hands and fallen back on language" in *Burton*. *Sullivan*, slip op. at 15. As in *Sullivan*, the lower court's reliance in this case on the broad language of *Burton* ignores this Court's subsequent

limitation of that decision to its facts. *See Sullivan*, slip op. at 16; *Blum*, 457 U.S. at 1011; *Jackson v. Metropolitan Edison Co.*, 419 U.S. 345, 357-58 (1974). Medicare HMO contractors "are at least as extensively regulated as the private nursing facilities in *Blum* and the private utility in *Jackson*. Like those cases, though, the [federal] statutory and regulatory scheme leaves the challenged decisions to the judgment of [HMOs]." *Sullivan*, slip op. at 16.

II. THE NINTH CIRCUIT'S "DUE PROCESS" HOLDING CONFLICTS WITH *SULLIVAN* AND *MATHEWS V. ELDRIDGE*

In concluding that due process justified the procedures imposed by the district court's injunction, the court of appeals implicitly assumed that Medicare beneficiaries who voluntarily enroll in HMOs have a constitutionally protected property interest in receiving medical treatment. *See Sullivan*, slip op. at 18 ("Only after finding the deprivation of a protected interest do we look to see if the State's procedures comport with due process."). *Sullivan*, however, invalidates that assumption. Just as the employees in *Sullivan* had no property right to demand payment for medical treatment until they established that the treatment was both reasonable and necessary, *id.* at 19, Medicare HMO enrollees have no property right to demand the provision or continuation of medical treatment that has not been determined to be a covered benefit under their HMO contracts.

Even if its underlying assumption of a protectable property interest were correct, however, the Ninth Circuit erred in its failure properly to apply the balancing test required by *Mathews v. Eldridge*, 424 U.S. at 335. The court paid mere lip service to the "government interest" factor, asserting conclusorily that the Secretary had "failed to show that the added procedural protections sought by [respondents] would result in significant additional costs to the government." Pet. App. 17a. The court ignored completely the additional costs to the HMOs, and the effect those additional costs would have on Medicare beneficiaries, the Medicare program and the federal budget. Indeed, it ignored

the essential goal of the Medicare managed care program: to reduce Medicare costs and add benefits by taking advantage of "the health benefit design, delivery and cost containment innovations that have occurred in the private sector" and that have "helped the private market contain costs and expand health care delivery options." *See* H.R. CONF. REP. NO. 105-217, at 585, *reprinted in* 1997 U.S.C.C.A.N 176, 206.

As regulatory and administrative mandates are increased, they impair the ability of HMOs to obtain the efficiencies and offer the benefits that Congress envisioned. Indeed, under the method used to calculate the capitation payments to HMOs for Medicare enrollees, any increase in administrative costs will directly reduce the amount available to cover lower premiums for enrollees or to provide benefits, such as prescription drugs, that are not covered by fee-for-service Medicare. *See* 42 U.S.C.A. § 1395w-23(c) (Supp. 1998) ; S. Rep. No. 97-494, at 35, 1982 U.S.C.C.A.N. 781, 811. In the worst case, regulatory and administrative costs become so high that HMOs are driven out of the Medicare program entirely.

These concerns are more than theoretical. In the Fall of 1998, forty-five HMO plans that were eligible to transition to the Medicare+Choice program on January 1, 1999, decided to withdraw from the program, and fifty-four plans decided to cut back their services. *Forty-Five HMOs Leave Program, 54 Reduce Service for 1999, HCFA Reports*, 6 BNA HEALTH CARE POL'Y REP. 1955, 1955-56 (1998). In all, about 400,000 (or approximately 6.5% of the more than 6 million) Medicare risk-sharing enrollees were affected. *Id.* This mass exodus was primarily the result of the program's revised payment methodology combined with significant costs and burdens resulting from new program regulatory requirements.

By constitutionalizing the internal grievance and appeal procedures applicable to private Medicare HMO plans, the courts below have further increased those regulatory costs in a

manner not contemplated by Congress or the Secretary.[6] Those increased costs will ultimately redound to the detriment of the very beneficiaries that the lower courts were purporting to protect. As the then-Director of HCFA's Office of Managed Care (which is responsible for administering the Medicare managed care program) explained to the district court, various provisions of the injunction

> could have adverse results for beneficiaries by distracting physicians and other health professionals from the provision of care, and by increasing administrative costs to the point where medical benefits beyond those required by the Medicare program (e.g. prescription drug coverage, annual physical exams, eye and ear care, etc.) are cut. Other potential results are higher premiums and

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[6] For example, the injunction provides that when there is a denial of "acute care services" (which the injunction does not define), the medical services in dispute must continue until a final reconsideration decision is made. Pet. App. 63a. As pointed out by the then-Director of HCFA's Office of Managed Care, this provision would create a tremendous incentive for enrollees to request reconsideration regardless of the merits, since the services would be covered until the reconsideration process was completed. Aside from the additional administrative costs that HMOs would incur as a result of such meritless appeals, HMOs would be forced to pay for the provision of medically unnecessary care. This is evidenced by the fact that since 1995, more than two-thirds of HMO service denial decisions have been upheld on reconsideration. 2d Fried Decl. ¶ 10.

Another problematic aspect of the injunction is the requirement that written notice be given within five days of *any* request, *oral* or written, for treatment services (Pet.App. 60a). It will often be difficult to differentiate between "official" oral requests for services and mere "give and take" discussions between a patient and a provider about treatment options or advice. If an HMO is bound to provide written denials in connection with any encounter in which the efficacy of a specific type of treatment is discussed, a great deal of additional paperwork will be required. This would significantly burden HMOs by diverting administrative and provider resources with no corresponding benefit to patients. 2d Fried Decl. ¶ 8.

> beneficiary copayments, and even withdrawal of HMOs from the Medicare managed care program.

2d Fried Decl., ¶ 13.

In disregarding these concerns, and in summarily rejecting the Secretary's determination of the appropriate balance between cost-effective health care delivery and patient rights, the courts below violated this Court's admonition in *Mathews* that "[i]n assessing what process is due in [a particular] case, substantial weight must be given to the good-faith judgments of the individuals charged by Congress with the administration of social welfare programs that the procedures they have provided assure fair consideration of the entitlement claims of individuals." 424 U.S. at 349. This principle applies with particular force to the Medicare managed care program, which requires difficult compromises among competing goals and interests—a function that the judicial branch is simply not designed to perform. In these circumstances, the lower courts' apparent failure to give any weight, much less substantial weight, to the good-faith judgments of those who administer the Medicare managed care program warrants summary reversal of the decision below.

CONCLUSION

The petition for a writ of certiorari should be granted, and the decision below should be summarily reversed and the injunction vacated in light of this Court's decisions in *American Manufacturers Mutual Insurance Co. v. Sullivan*, No. 97-2000 (U.S. Mar. 3, 1999), *Blum v. Yaretsky*, 457 U.S. 991 (1982) and *Mathews v. Eldridge*, 424 U.S. 319 (1976). In the alternative, the petition should be granted, and the Court should review and reverse the decision below on the merits.

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IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1998

DONNA E. SHALALA,
SECRETARY OF HEALTH AND HUMAN SERVICES,
Petitioner,

v.

GREGORIA GRIJALVA, *et al.*,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

BRIEF OF AMICUS CURIAE AMERICAN ASSOCIATION OF HEALTH PLANS IN SUPPORT OF PETITIONER

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INTEREST OF THE AMICUS

Amicus curiae respectfully submits this brief in the support of Petitioner. Amicus curiae, the American Association of Health Plans, Inc. ("AAHP"), is a non-profit trade association representing approximately 1,000 managed care companies, many of whom are currently involved in the Medicare program throughout the United States. AAHP's principal purpose as a trade association is to foster, encourage and assist development of an organized, pre-paid healthcare system as an alternative to other arrangements for the delivery of healthcare services. AAHP's brief focuses on two of the questions presented: Issue 1 (whether the denial by private health maintenance organizations ("HMOs") of healthcare services under the Medicare Program constitutes government action) and Issue 3 (whether the Court should vacate the judgments below in light of the new legislation and regulations governing Medicare). AAHP also addresses the impact that the decision below will have if the Court does not vacate it.[1]

By participating in this action, AAHP seeks to protect its members' rights. AAHP is concerned that, if the lower court judgments in this case are upheld, the imposition of "government actor" status on private healthcare companies could have a far-reaching impact on all managed care organizations who participate in publicly-funded programs. The judgments will impose costly administrative requirements on Medicare HMOs in all aspects of their operations. In addition, as a result of the broad

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[1] Pursuant to Supreme Court Rule 37.6, AAHP states that no counsel for a party authorized this brief in whole or part; and that no person or entity, other than the amicus and its counsel, contributed monetarily to the presentation or submission of this brief. The consents to the filing of this amicus brief in this proceeding have been filed with the Clerk.

application of the government action doctrine by the courts below, the decisions in this case are likely to be the basis of even more attenuated claims of government action in the future. Indeed, at least one Medicaid healthcare provider has already cited the district court's decision as a basis for challenging the non-renewal of contracts. The decisions will also inevitably expand the grounds for beneficiary litigation challenging medical decisions, benefit changes, coverage determinations and review procedures.

In addition, the court of appeals' decision will likely have an adverse impact on the new "Medicare+Choice" program and Medicare beneficiaries. The expansive application of the government action doctrine to private healthcare companies will discourage participation in the Medicare+Choice program by health plans and their affiliated providers.

STATEMENT OF CASE

This action involves the coverage of medical care by HMOs under the Medicare program. Respondents sought declaratory and injunctive relief against Petitioner, the Secretary of the Department of Health and Human Services ("the Secretary"), for allegedly failing "to enforce due process requirements," and "to monitor HMO denials of medical services to enrolled Medicare beneficiaries." *Grijalva v. Shalala*, 152 F.3d 1115, 1117 (9th Cir. 1998).

At the time of the district court litigation, HMOs participated in the Medicare program under "risk-sharing" agreements pursuant to 42 U.S.C. §1395mm(g). Congress has since abolished that program and replaced it with the new Medicare+Choice program. Under the former risk contracts, HMOs were paid a fixed monthly

payment for each Medicare beneficiary who chose to enroll in the HMO. The fixed monthly premium rates were based, in large part, on the fee-for-service costs necessary to provide the basic Medicare benefits. Risk-sharing HMOs were also required to submit an "adjusted community rate" ("ACR") to the Secretary each year. The ACR represents the amount the HMO would charge in the open market for a package of basic Medicare benefits. 42 U.S.C. §1395mm(e)(3). If the ACR for the basic Medicare benefits was below the monthly rate, an HMO could either refund the difference to the government or provide "additional benefits" to beneficiaries valued at the difference between the HMO's ACR and the Medicare premium. 42 U.S.C. §1395mm(g)(2).[2] Traditionally, HMOs added benefits and reduced or eliminated any co-payment due from the beneficiary. Accordingly, Medicare risk-sharing HMOs generally provided beneficiaries with the basic Medicare benefits under the statute plus additional benefits at no additional charge to the government or the beneficiary.

The Secretary did not adjust monthly payments based on the services actually utilized by beneficiaries. Rather, the risk-sharing Medicare HMOs bore the risk that increased patient needs and attendant costs could exceed the fixed monthly payments received for each Medicare beneficiary. These risk-sharing components of the Medicare contracts were similar to HMO coverage purchased by individuals or employers for their employees in the commercial market.

Respondents below alleged that Petitioner failed to enforce adequately her statutory and due process obliga-

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[2] Under the risk-sharing contracts, HMOs were also permitted to provide additional benefits for a premium charged to Medicare enrollees subject to the express approval of the Health Care Financing Administration ("HCFA"). *Id.* at §1395mm(c)(2).

tions under the Medicare statute and regulations when HMOs denied coverage for claims submitted by Medicare beneficiaries. The district court held that Respondents' "claim hinge[d] on whether HMO denials of service constitute[d] state action." *Grijalva v. Shalala*, 946 F. Supp. 747, 751 (D. Az. 1996). Finding state action, the district court granted Respondents' motion for summary judgment, ruling that the notices of denial of coverage were difficult to understand. The court issued an injunction specifying the type of written notice required for coverage denials and the time requirements necessary to comport with the due process mandates of the Fifth Amendment. The injunction also mandated that the Secretary monitor and investigate compliance with the court's notice requirements, and barred the Secretary from renewing contracts with any HMO that did not comply with the provisions of the court's order. The Court of Appeals for the Ninth Circuit upheld the district court's decision, relying heavily on the district court's reasoning.

On August 5, 1997, while the appeal was pending, Congress passed the Balanced Budget Act of 1997 ("BBA"), Pub. L. No. 105-33, Sec. 4001-4002, 111 Stat. 275-330. The BBA eliminated all risk-sharing contracts and thereby effectively repealed Section 1395mm(g), the statutory provision at issue in this case. Congress replaced risk-sharing contracts with the Medicare+Choice program. The BBA also eliminated the Secretary's authority to renew risk-sharing contracts as of January 1, 1999. Pursuant to the new law, the Secretary promulgated regulations to implement the new Medicare+Choice program.

Petitioner filed her Writ for Petition of Certiorari on February 11, 1999. Petitioner requested that the Court hold the Petition until the Court issued its opinion in

American Manufacturers Mutual Insurance Co., et al. v. Sullivan, et al., 526 U.S. ____, No. 97-2000, (March 3, 1999) (slip op.). Now that the Court has issued its ruling in *Sullivan*, the Court should grant Petitioner's writ. The Court should vacate the court of appeals' decision, direct the court of appeals to vacate the district court's injunction, and remand the case to the district court for consideration of the Respondents' claims in light of the *Sullivan* decision, the passage of the BBA and the regulations promulgated thereunder.

SUMMARY OF ARGUMENT

1. The Court Of Appeals' Ruling Is Inconsistent With The *Sullivan* Decision

This Court's recent opinion in *Sullivan* rejected the very factors that the lower courts in the instant case employed to evaluate potential government action, including "joint participation" in a program and extensive government regulation. *Sullivan*, slip op., at 16. Moreover, as this Court reaffirmed in *Sullivan*, private decisions regarding medical benefits, as are at issue here, are not the type of action traditionally taken by the government. Rather, such action is traditionally "made by concededly private parties, and 'turns on . . . judgments made by private parties' without 'standards established by the State.' " *Sullivan*, slip op., at 11 (quoting *Blum v. Yaretsky*, 457 U.S. 991, 1008 (1982)). Accordingly, the court of appeals decision below, finding that an HMO assumes the role of a government actor when it denies coverage of a medical benefit for a Medicare beneficiary, runs afoul of this Court's decision in *Sullivan*.

2. HMO Actions That Violate The Medicare Statute Do Not Constitute Government Action

Respondents contend below that the HMOs' written coverage determinations did not provide the procedural safeguards mandated by the Medicare statute and regulations, and that the Secretary failed to enforce those safeguards. The courts have previously held that actions by a private party in violation of statutory authority or administrative regulations do not constitute government action. *Starnes v. Capital Cities Media, Inc.*, 39 F.3d 1394, 1397 (7th Cir. 1994) (citing *Lugar v. Edmondson Oil Co.*, 457 U.S. 922, 937 (1982)). As this authority demonstrates, the HMO coverage decisions at issue do not constitute government action to the extent that HMOs acted outside of the statutory and regulatory requirements imposed by the Medicare Act.

3. The Decisions Will Have Unfavorable And Far-reaching Effects

If the court of appeals' holding in this case is permitted to stand, serious adverse consequences will result. If the requirements for participation in the Medicare+Choice program are to be dictated, in part, by the application of the government action doctrine by individual courts on an *ad hoc* basis, many HMOs will be discouraged from participating or from continuing to participate in such an unsettled regulatory environment.

The decision below also is likely to spawn litigation by providers as well as beneficiaries. Providers already have argued, based on the decisions below, that HMOs act as the government's proxy when choosing the providers with whom they wish to contract for purposes of Medicaid. *Catanzano v. Wing*, 103 F.3d 223, 227 (2d Cir. 1996).

That case demonstrates the breadth of the decisions below and the seemingly limitless application of those decisions unless they are vacated.

4. The Balanced Budget Act Of 1997 Mandates The Case Be Vacated And Remanded

In August 1997, Congress passed the Balanced Budget Act ("BBA"). This Act abolished "risk-sharing" HMOs in the Medicare Program as of January 1, 1999. Moreover, the BBA established enhanced notice and appeal opportunities to beneficiaries under the Medicare+Choice program. As a result, the court of appeals based its decision on a program that no longer exists. The BBA's abolishment of the statutory basis for the district court and the court of appeals' decisions mandates that this case be remanded to consider the BBA and the Secretary's new regulations.

REASONS FOR GRANTING THE PETITION

I.

THE COURT OF APPEALS' RULING SHOULD BE VACATED IN LIGHT OF THIS COURT'S RECENT RULING IN THE *SULLIVAN* CASE.

The lower courts' decisions are at odds with the opinion issued by this Court on March 3, 1999, in *American Manufacturers Mutual Insurance Company, et al. v. Sullivan*, 526 U.S. ___ , No. 97-2000 (March 3, 1999) (slip op.). In *Sullivan*, this Court rejected the Third Circuit's application of the state action doctrine to private insurers seeking utilization review of treatment requests for individuals receiving workers' compensation benefits. That ruling is controlling over the instant case and calls for the Court to vacate the court of appeals' decision here.

The issues in both cases are nearly identical. In *Sullivan*, the Court considered "whether a *private insurer's* decision to withhold payment for disputed medical treatment may be fairly attributable to the State so as to subject insurers to the constraints of the Fourteenth Amendment." *Sullivan*, slip op., at 10 (emphasis in original). Similarly, in the instant case, one of the issues before the Court is:

> [w]hether the decision by a Section 1395mm(g) HMO to deny an enrolled Medicare beneficiary's request for health services constitutes government action subject to the requirements of the Due Process Clause of the Fifth Amendment.

Pet. Br. at I. Both cases turn on whether health benefits coverage determinations by private entities, in one case workers' compensation insurers and in the other Medicare HMOs, constitute government action. The Court in *Sullivan* answered this question "no." *Sullivan*, slip op., at 10.

The courts below failed to apply the appropriate standards for analyzing claims of government action by private entities. In a series of decisions over the past thirty years, this Court has established the proper analytical framework and standards to determine whether it is appropriate to impose on federal and state officials responsibility for the conduct of private parties. The benchmarks for establishing government action are not easily met in order to protect private citizens' actions against the unfair imposition of constitutional restraints, and to avoid "imposing on the states, its agencies or officials, responsibility for conduct which they cannot fairly be blamed." *Lugar*, 457 U.S. at 936-937.

As recently reaffirmed in *Sullivan*, this Court established two prerequisites for imposing due process requirements on private entities acting as a proxy for the

government. First, the challenged activity must be "caused by the exercise of some right or privilege created by the State or by a rule of conduct imposed by the [government] or by a person for whom the [government] is responsible." *Sullivan*, slip op., at 8 (quoting *Lugar*, 457 U.S. at 937); *also see*, *Flagg Bros., Inc. v. Brooks*, 436 U.S. 149, 156 (1978). Second, "the party charged with deprivation must be the person who may fairly be said to be a [government] actor." *Ibid.* In the case before the Court, the Medicare statute established the rights at issue. Accordingly, Respondents likely satisfy the first prong of the test to determine government action. Respondents fail, however, to fulfill the second prong—identifying a party that is acting as a proxy for the federal government.

The court of appeals based its finding of government action on the contention that risk-sharing HMOs and the Secretary "jointly participated" in the Medicare program. *Grijalva*, 152 F.3d at 1119-1120. The court of appeals' reliance on the "joint participation" theory is misplaced. In *Sullivan*, this Court reversed a Third Circuit decision that relied on the same joint participation theory as relied upon by the court of appeals in the instant case. The Third Circuit ruled that the Pennsylvania workers' compensation system "inextricably entangles the insurance companies in a partnership with the Commonwealth such that they become an integral part of the state in administering the statutory scheme." *Sullivan v. Barnett*, 139 F.3d 158, 170 (3d Cir. 1998), *rev'd*, 526 U.S. ___ (1999). The *Sullivan* Court rejected "joint participation" between insurance companies and the State as a basis for establishing government action. *Sullivan*, slip op., at 16-17.

The mere invocation of "joint participation" is insufficient to establish government action. Rather, the courts

must assess the facts and the specific allegations made by the plaintiff that give rise to the claim. *Ibid.* The courts determine whether the government "has exercised coercive power or has provided such significant encouragement, either overt or covert, that the choice must in law be deemed to be that of the State." *Id.*, slip op., at 10 (quoting *Blum*, 457 U.S. at 1004). This Court recognizes that action taken with "mere approval or acquiescence" of the government is not sufficient to create government action. *Ibid.*

The court of appeals below identified five facts in support of its finding of joint participation between the Secretary and risk-sharing HMOs. None of these facts, however, when analyzed in light of this Court's prior decisions, support the lower court's finding that Medicare HMOs were acting as a proxy for the Secretary.

First, the court of appeals stated that the government regulates HMOs' activities as they apply to Medicare beneficiaries, especially benefit coverage determinations. *Grijalva*, 152 F.3d at 1120. This Court has consistently held, however, that extensive regulation of an industry does not render private actions by members of that industry government action subject to constitutional restrictions. *Sullivan*, slip op., at 10; *Blum*, 457 U.S. at 1004; *Jackson v. Metropolitan Edison Co.*, 419 U.S. 345, 350 (1974). If simple imposition of government regulations created government action, then virtually every action by an HMO would be classified as such. HMOs are regulated under federal and state law. Moreover, many healthcare plans provided by HMOs are provided through employer groups and are governed by the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. §§1001, *et seq.* (1999). These provisions frequently impose mandates that include providing certain appeal rights to subscribers to protest any medical coverage

determinations made by an HMO. *See, e.g.*, ERISA, 29 U.S.C. §1133 (1999); *see also*, Md. Code Ann., Ins. Art §15-10A-02 (1997 & Supp. 1998). If each of these requirements transformed HMO coverage decisions into government action, then little of what HMOs do would escape the due process requirements of the Fifth or Fourteenth Amendment. As the Court made clear in *Sullivan*, such expansive applications of the government action doctrine are disfavored.

Second, the courts below relied on the fact that the Secretary issued regulations regarding internal appeal processes under the Medicare program to demonstrate joint participation. *Grijalva*, 152 F.3d at 1120. Yet, this is no different from the prior factor—there is a substantial regulatory framework governing Medicare. The Court has previously held that this type of regulatory framework, and the fact that participants must operate within that framework, does not convert otherwise private action into government action. *Blum*, 457 U.S. at 1000. Moreover, the internal appeal processes are common to HMOs and not unique to Medicare. In private contracts, HMOs often provide similar, if not identical, internal appeals processes. Accordingly, this fact indicates traditional private action, not action attributable to the sovereign.

Third, the courts below found that the Secretary has delegated medical coverage decisions to HMOs. *Grijalva*, 152 F.3d at 1120. The Secretary, however, could not delegate these decisions because they were never hers to make. The Medicare statute specifically prohibits the "exercise [of] any" governmental "supervision or control over the practice of medicine or the manner in which medical services are provided." 42 U.S.C. §1395. Given this prohibition, the independent determinations of medical coverage by HMOs participating in the Medicare program cannot fairly be attributed to the Secretary.

Moreover, in *Sullivan*, the Court rejected this precise argument as an overly simplistic approach to addressing government action.

> Such permission of a private choice cannot support a finding of state action. As we have said before, our cases will not tolerate 'the imposition of Fourteenth Amendment restraints on private action by the simple device of characterizing the State's inaction as authorization or encouragement.'

Sullivan, slip op., at 12 (quoting *Flagg Bros.*, 436 U.S. at 164-165). Neither Respondents nor the courts below have demonstrated that HMOs fail to exercise independent judgment when denying claims based on issues of medical appropriateness, necessity or coverage.

To be considered government action, these medical coverage decisions must be both traditionally and exclusively a government function. *Blum*, 461 U.S. at 1005; *Jackson*, 419 U.S. at 353; *see*, *Flagg Bros.*, 436 U.S. at 157-161. Such exclusive functions would include conducting elections, *Edmonson v. Leesville Concrete Co.*, 500 U.S. 614, 624 (1991), exercising the power of eminent domain, *Jackson*, 419 U.S. at 352-354, or governing a city or a town, *Marsh v. Alabama*, 326 U.S. 501 (1946). Decisions as to the medical appropriateness of care are not a "traditional government function," giving rise to government action. *Edmonson*, 500 U.S. at 622.

To the contrary, HMOs, not the government, make determinations every day regarding the medical appropriateness and necessity of medical treatment. HMOs routinely make these decisions in commercial relationships as well as government-sponsored health benefits programs. As the Court pointed out in *Sullivan*, this function is a "traditionally private prerogative" that, no matter how it is characterized, does not constitute government action. *Sullivan*, slip op., at 15. Simply put, the "day-to-

day" determinations of healthcare benefits is not a function that is "traditionally the exclusive prerogative of the state." *Blum*, 457 U.S. at 1005 (citing *Jackson*, 419 U.S. at 353).

Fourth, the court of appeals found that HMOs' coverage decisions were government action based, in part, on the fact that the government "pays HMOs for each enrolled Medicare beneficiary . . ." *Grijalva*, 152 F.3d at 1120. Yet, the identity of the payor of benefits is not germane to the issue of whether or not risk-sharing HMOs under the Medicare program are government actors. As the Court affirmed in *Sullivan*, there are two prerequisites for determining when private action constitutes government action. The first factor is whether the right or privilege at issue is created by the government. *Sullivan*, slip op., at 8; *also see*, *Lugar*, 457 U.S. at 937. The fact that Medicare is federally funded may satisfy this factor. This funding, however, does not affect the second factor, whether the private party can be considered a "government actor." *Blum*, 457 U.S. at 1011. As the Court held in *Blum*, the funding of a program does not affect whether or not the actions of a private party are considered government acts. *Ibid.*

Finally, the court of appeals found that the fact that Medicare beneficiaries can appeal HMO service denials directly to the Secretary who "has the power to overturn the HMO's decision" was pertinent to the government action analysis. *Grijalva*, 152 F.3d at 1120. To the contrary, if the mere fact that private decisions by HMOs can ultimately be appealed to and overturned by some government authority, administrative body or court was attributable to the government, then almost all coverage decisions by HMOs constitute government action. Coverage decisions can almost always be appealed to various state administrative agencies, state courts, or federal

courts. Indeed, this Court did not find government action in the *Sullivan* case even though employees could appeal the workers' compensation insurance determinations to a workers' compensation administrative law judge for *de novo* review. *Sullivan*, slip op., at 5. Similarly, the availability of an appeal to the Secretary of an initial coverage determination by an HMO does not render the HMO's original determination government action.

In sum, the facts relied on by the court of appeals in its decision do not justify the conclusion that private determinations as to medical coverage by HMOs constitute government action. Rather, decisions regarding medical coverage have been traditionally private action. In fact, the very Medicare statute that the court of appeals relied on for finding government action specifically prohibits the Secretary from supervising or controlling such decisions.

II.

HMOs' PRIVATE ACTIONS, TO THE EXTENT THEY VIOLATE THE MEDICARE STATUTE AND REGULATIONS, DO NOT CONSTITUTE GOVERNMENT ACTION

The courts have recognized that a state or federal agency cannot be held liable for actions of a private party in violation of that agencies' regulations or authorizing statutes. *Starnes v. Capital Cities Media, Inc.*, 39 F.3d 1394, 1397 (7th Cir. 1994) (citing *Lugar*, 457 U.S. at 937) ("Misuse of state law is not, however, state action for the purposes of the Fourteenth Amendment."); *cf.*, *Flagg Bros.*, 436 U.S. at 166 (a state's refusal to act does not constitute state action under the Fourteenth Amendment). By its very definition, private actions taken in violation of statutory or regulatory mandates are not undertaken at the "coercive power" or through "significant encouragment" of state or federal agencies. *Blum*, 457 U.S. at 1004.

Yet, in essence, that is what Respondents alleged in their complaint below. Respondents complained that HMOs were not abiding by the Medicare statute and the Secretary's regulations in providing benefits, notice of denials and other procedural safeguards. According to the court of appeals, Respondents sought declaratory injunctive relief against the Secretary for failing "to enforce due process requirements," and "to monitor HMOs and ensure that HMOs provided Medicare covered benefits." *Grijalva*, 115 F.3d at 1117. The actions complained of by Respondent cannot, by definition, constitute government action subject to constitutional mandates of due process.[3] HMOs allegedly acting in violation of the statutory and regulatory mandates under the Medicare program can hardly be deemed as acting as a proxy for the Secretary.

II

PERMITTING THE COURT OF APPEALS' THEORY OF GOVERNMENT ACTION TO STAND WILL HAVE FAR-REACHING UNFAVORABLE IMPLICATIONS

If the court of appeals' holding in this case is permitted to stand, serious adverse consequences will result. The court of appeals' decision below is an expansive and unwarranted application of the government action doctrine. In addition, the injunction is nationwide resulting from a national class action. The variegated potential implications of the decisions below alone warrant close examination of the Petition in this case.

The court of appeals' decision discourages HMO participation in Medicare. Medicare+Choice plans contracted with the Secretary based on the understanding they were subject to the statutory and regulatory requirements of the Medicare program. The decisions below threaten to

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[3] The only exception to this is Respondents' complaint that the regulatory appeal process for denial of "emergency" benefits is not sufficiently expedited to afford beneficiaries due process.

scuttle the regulatory requirements developed by the Secretary and augment or replace those standards with others developed by the courts on an *ad hoc* basis pursuant to the government action doctrine. Current Medicare+Choice participants are left uncertain as to the regulatory framework in which they are operating. Prospective Medicare+Choice plans must decide whether to join the program in the face of an unsettled regulatory scheme that, according to the court of appeals' decision, can be changed by claims of due process violations by Medicare beneficiaries.

In addition to this uncertainty, each additional due process requirement imposed by the courts will create additional financial and administrative burdens on HMOs, further limiting the willingness of HMOs and other private organizations to participate in the Medicare+Choice program. At a minimum, these increased costs could result in decreased benefits to Medicare beneficiaries. A decrease in participation by HMOs in the Medicare+Choice program will reduce the choice of plans and potentially limit the benefits available to beneficiaries.

The remedies mandated by the district court will also adversely impact the Medicare program, beneficiaries and participating HMOs. The district court's injunction requires HMOs to give beneficiaries written notice whenever a coverage determination results in a service or referral requested by a healthcare provider or enrollee being denied, or an ongoing course of treatments being reduced or terminated. Pet. Br. at 7, Pet. App. at 60a. The injunction in place appears to require HMOs to provide notice of each reduction or termination of a health benefit, even if ordered by the beneficiary's healthcare provider because his or her condition has improved to the degree that the benefit is no longer

necessary. Requiring notice in such situations will only serve to confuse beneficiaries and burden HMOs.

The injunction may also require a similar notice if an HMO changes its Medicare benefits. HMOs currently provide services in addition to the standard benefits mandated under the Medicare Act. HMOs provide these services based upon a comparison of the Medicare rates to the costs of such benefits in the commercial market. An HMO may alter its benefits in any given year to reflect the commercial market realities. Under the injunction, it is unclear whether an HMO can effectuate a reduction or elimination of any benefit without a due process notice and hearing.

Equally alarming is the district court mandate prohibiting the Secretary from renewing contracts with HMOs that fail to comply the court's notice requirements. *Grijalva,* 946 F. Supp. at 760. As explained above, the notice requirements imposed by the district court are vague and flawed. HMOs may fail to comply with the notice provisions, not out of neglect or other wrongdoing, but rather because of misunderstandings as to the notice requirements. The draconian sanction of non-renewal of contracts imposed by the district court, if upheld, will create a serious disincentive for HMOs currently participating in the program as well as for those plans considering future participation in Medicare+Choice. Moreover, once a contract is not renewed, the HMO is precluded from participating in the Medicare Program for five years. 42 U.S.C. §1395w-27(c)(4).

The court of appeals' decision below will also undoubtedly become a launching pad for new litigation to challenge Medicare+Choice HMOs' actions in the courts. Providers will now argue that HMOs are acting as a proxy for the Secretary when they determine the providers with

whom they wish to contract. As such, providers will contend that they are all entitled to due process before HMOs can decide not to enter into a contract or renew a contract with the provider. Indeed, at least one Medicaid provider has already cited the decisions below for the proposition that a health plan contracting with a state Medicaid program is a government actor that must provide procedural due process before deciding not to renew a provider's contract. *Catanzano*, 103 F.3d at 227.

In sum, it is foreseeable that decisions other than coverage determinations, e.g., decisions about administrative policy, changes in benefit packages, exiting a service area or terminating provider contracts, could also implicate substantive or procedural due process rights under the lower courts' decisions. The outgrowth of those decisions may very well circumvent the balance of interests established under the BBA. Constitutionalizing the private relationship between providers and HMOs also disturbs an area traditionally defined by contract, and to some degree, by statute and regulation.

IV.
THE BALANCED BUDGET ACT OF 1997 MANDATES THE CASE BE VACATED AND REMANDED

In August 1997, Congress passed the BBA. This Act abolished risk-sharing HMOs in the Medicare Program as of January 1, 1999, and effectively repealed the statutory provision at issue in this case. The BBA, in addition to eliminating risk-sharing HMOs, established enhanced regulations governing the notice and appeal opportunities provided to beneficiaries by HMOs participating in the Medicare+Choice program. In short, the BBA and the regulations promulgated thereunder addressed the concerns raised by the courts below. As a result, the deci-

sions below must be remanded to address the notice and appeal issues under the new statutory and regulatory framework.

The BBA and the regulations promulgated thereunder, now require, *inter alia*, understandable written notices of decisions, 111 Stat. 293 (Section 1852(g)(1); 42 C.F.R. 422.568(d)); medical necessity decisions made by qualified medical personnel, 111 Stat. 293 (Section 1832(g)(2)(B); 42 C.F.R. 422.590(g)(2)(B)); and timely initial and reconsideration decisions. 111 Stat. 293-294 (Section 1852(g)(2) and (3); 42 C.F.R. 422.568(a), 422.572, 422.590(a)-(d)). These are precisely the issues that Respondents included in their complaint and that the district court addressed in its injunction.

These new provisions supersede the regulatory scheme that existed for risk-sharing HMOs and therefore eradicate the need for injunctive relief in this case. As this Court and the Petitioner have rightly stated, the law has " 'been sufficiently altered' pending appeal 'so as to present a substantially different controversy than the one the [lower courts] originally decided.' " Pet. Br. at 35 (quoting *Northeastern Fla. Chapter of the Associated Gen. Contractors v. City of Jacksonville*, 508 U.S. 656, 662 n.3 (1993); *id.* at 670-671 (O'Connor, J., dissenting)). The BBA's abolishment of the statutory basis for the district court and court of appeals' decisions, coupled with this Court's decision in *Sullivan*, mandate that the judgment of the court of appeals be vacated and remanded to the district court.

CONCLUSION

The courts below improperly held that coverage determinations made by Medicare HMOs constitute government action. Consistent with the *Sullivan* decision, neither the Respondents nor the court of appeals can transform these private decisions into federal action. Accordingly, the Court should grant the Petition for Writ of Certiorari, vacate the judgment of the court of appeals, direct the court of appeals to vacate the judgment of the district court and remand the case to the district court for further review in light of the *Sullivan* decision, the BBA and its implementing regulations.

Respectfully submitted,

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No. 98-1284

In The

Supreme Court of the United States

October Term, 1998

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES,

Petitioner,

v.

GREGORIA GRIJALVA, MARY LEA, JOSEPHINE BALESTRERI, FRED S. SCHERZ, KEVIN A. DRISCOLL, MINA AMES, EDMUNDO B. CARDENAS, ARLINE T. DONOHO, GOLDIE M. POWELL, and RICHARD BAXTER, as individuals and representatives of a class of persons similarly situated,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

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REVISED STATEMENT OF QUESTIONS PRESENTED

Respondents suggest that a more accurate statement of the Questions Presented, both in content and in recognition of the Secretary's goal with this Petition, is as follows:

Whether the judgments below should be vacated, and the case remanded to the district court to begin the litigation anew, because of either (1) legislation which the Secretary explicitly declined to rely on in the court of appeals, which has made no significant change to the relevant portions of the Medicare statute, and which the Secretary has misrepresented to the Court, or (2) a recent decision of this Court which, upon objective scrutiny, has no bearing on the outcome of the instant case.

Whether the courts below correctly concluded, like other courts considering government health services delivered by HMOs, that when the federally created, mandated, and operated Medicare program contracts with private HMOs to provide Medicare benefits, their coverage decisions constitute state action.

Whether the courts below correctly concluded that the Secretary violated principles of due process, which have been recognized as a requirement in the Medicare program by numerous courts, when she did not require her contracting HMOs to provide adequate notice and hearings upon the reduction or termination of Medicare benefits.

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§ 410.1-410.175 5

§ 417.1-417.694 7

MISCELLANEOUS:

62 Fed. Reg. 23368 (April 30, 1997) 11

McIlrath, *GAO Report, Medicare HMOs*, American Medical News 3 (November 18, 1996) 6

Report of testimony by Bruce C. Vladek, HCFA Administrator, at February 10, 1995 hearing of the Health Subcommittee of the House Ways and Means Committee, reported at 842 New Developments 5-7, Medicare & Medicaid Guide (CCH) 7

Rule 60(b), F.R.Civ.P. 26

S. J. Stayn, *Securing Access to Care in HMOs: Toward a Uniform Model of Grievance and Appeal Procedures*, 94 COLUM. L. REV. 1674 (1994) 8

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INTRODUCTION

The Secretary argues that a writ of certiorari should be issued for two reasons, neither of which is well taken.

The facts and legal context of *American Manufacturers Mutual Insurance Co. v. Sullivan,* 119 S.Ct. 977 (1999), differ so dramatically from those in the instant case that *Sullivan* has no bearing on the state action issue. Here, in contrast to the workers' compensation program at issue in *Sullivan,* Medicare's status as a public entitlement mandated by congressionally established substantive standards, to which due process protections have always attached, compels the finding of state action which the courts below correctly made.

In addition, for several reasons, it is not necessary or appropriate for the decisions below to be vacated and the case remanded in light of the Balanced Budget Act (BBA), which was passed and in effect before briefing was completed in the court of appeals. First, the Secretary explicitly declined to raise this issue at the appropriate time below, apparently viewing the BBA as not relevant to the issues here raised. Second, any apparent compliance by the BBA and its implementing regulations with the judgment below responded only in small part to the deficiencies identified by the district court. Third, as the court of appeals observed, the district court may modify its order in light of later developments if the Secretary so requests and the legal standards are met; that procedure, not the vacating of the judgments below without full briefing and in the face of inaccurate and misleading statements by the Secretary, is the appropriate procedure for resolving these issues.

Furthermore, although the Secretary suggests that this case might be appropriate for plenary review, she is in error: there is no conflict between the circuits on the issues raised in this case, and the court of appeals properly applied rules of law in the state action and due process contexts which have long been settled by this Court. Indeed, the Secretary's main effort is to manipulate the BBA and *Sullivan* as the mechanisms for negating lower court decisions with which she disagrees. In her eagerness to have the lower court opinions simply disappear, the Secretary has repeatedly mischaracterized the nature of the Medicare program and the content and relevance of the BBA. The petition for a writ of certiorari should be denied and the decisions below left intact.

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The Secretary asserts that the HMO portion of the Medicare statute in effect when the district court made its decision has been superseded by entirely new Medicare+Choice legislation. That is not correct. The HMO portion of the Medicare statute and program remains in effect, with only minor changes, renamed as one of the Medicare+Choice coordinated care options allowed by the Balanced Budget Act of 1997 (BBA), Pub. L. No. 105-33, § 4001, 111 Stat. 251, 275 (Social Security Act (S.S.A.) § 1851(a)(2)(A)). Compare BBA, §§ 4001-4002, 111 Stat. 275-330 (only partially set forth in Pet.App. 70a and 100a-101a) with the prior HMO provisions, 42 U.S.C. §§ 1395mm *et seq.* Because the Secretary failed to include significant and relevant portions of the BBA in her

Appendix, the current HMO portion of the Medicare statute, including the minor changes made by the BBA, is set forth as Respondents' Appendix (Resp.App.).

Although the BBA includes an expedited HMO reconsideration determination in its appeal procedures for Medicare HMO beneficiaries, S.S.A. § 1852(g), Pet.App. 93a-101a, this change complies with only one part of the district court's remedial order. The Secretary ignores the fact that four other important parts of that order remain unmet.

Also, contrary to the Secretary's description of Medicare HMOs as making coverage determinations according to their own professional and contractual obligations without government participation or assistance, Pet.Br. 16-17, 20, the Medicare statute specifies the health services provided to beneficiaries of the program. Under Part A, these services must include:

> (1) inpatient hospital services . . . for up to 150 days . . . ;
> (2)(A) post-hospital extended care services for up to 100 days . . . ;
> (3) . . . home health services; and
> (4) in lieu of certain other benefits, hospice care. . . .

42 U.S.C. § 1395d(a). Under Part B, services that Medicare must cover include:

> (A)(i) home health services . . . ;
> (B) medical and other health services [including physician services, outpatient

> therapies and diagnostic tests, home dialysis equipment, antigens, durable medical equipment, and ambulance services] . . . ;
>
> (C) outpatient physical therapy services . . . ;
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> (D) [certain health clinic services];
>
> (E) comprehensive outpatient rehabilitation facility services; and
>
> (F) facility services furnished in connection with surgical procedures specified by the Secretary. . . .

42 U.S.C. § 1395k(a)(2). These provisions remain intact under the BBA.

HMOs which contract with the Medicare program are required to provide their enrollees with the full range of services covered by Medicare for beneficiaries generally. 42 U.S.C. § 1395mm(c)(2)(A). This section also remains intact under the BBA.

Congress included a mandatory enforcement mechanism for the standards prescribed for Medicare HMOs: "The Secretary may not enter into a contract under this section with an eligible organization unless it meets the requirements of this subsection and subsection (e) of this section with respect to members enrolled under this section." 42 U.S.C. § 1395mm(c)(1). Again, this section remains intact under the BBA. Resp. App. 7.

STATEMENT OF THE CASE

1.a. The Medicare program, established by Congress in 1965, mandates that the federal government cover specific medical services for Medicare beneficiaries. The Secretary has issued extensive regulations and administrative manuals defining with precision the package of health services covered and the process by which coverage determinations are made pursuant to the statute. 42 C.F.R. §§ 409.1-409.68, 410.1-410.175. Incident to this legislative determination, the courts have definitively established that Medicare benefits are constitutionally protected property rights. *Schweiker v. McClure*, 456 U.S. 188, 198 (1982); *Mathews v. Diaz*, 426 U.S. 67 (1976).

In the traditional fee-for-service program, which has existed since Medicare's inception in 1965, health care providers are paid directly for services already rendered to Medicare beneficiaries. The Secretary contracts with private insurers, called "intermediaries" under Part A and "carriers" under Part B, to process claims and otherwise administer the benefits. These private insurers make coverage determinations including those related to medical necessity, make payments to providers and beneficiaries, establish guidelines and utilization screens for coverage, and investigate fraudulent billing practices. This Court has determined that, in exercising their contractual duties, the fiscal intermediaries act as the Secretary's agents. *McClure*, 456 U.S. at 190; see also, *e.g.*, *Bodimetric Health Services, Inc. v. Aetna Life & Casualty*, 903 F.2d 480, 487 (7th Cir. 1990).

From Medicare's beginning, Congress has required an administrative appeal process culminating in judicial review for beneficiaries who are denied benefits. 42 U.S.C. § 1395ff. The Secretary has promulgated detailed regulations governing this appeals process. 42 C.F.R. §§ 405.701 *et seq.* and 405.801 *et seq.* It has been clearly established that the requirements of procedural due process apply to the Medicare administrative appeals system. See, *e.g.*, *McCuin v. Sec. of H.H.S.*, 817 F.2d 161, 171-175 (1st Cir. 1987); *Gray Panthers v. Schweiker*, 652 F.2d 146 (1980), appeal after remand, 716 F.2d 23 (D.C.Cir. 1983); *Martinez v. Richardson*, 472 F.2d 1121 (10th Cir. 1973), on later motion, 655 F.Supp. 95, 102-103 (D.N.M. 1986) (reaffirming original judgment under updated due process analysis), appeal dismissed, 874 F.2d 751 (10th Cir. 1989).

In 1982, Congress authorized widespread Medicare contracting with risk-based HMOs. Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. No. 97-248, § 114(a), 96 Stat. 324, 341 (codified at 42 U.S.C. § 1395mm). Under this system, Medicare pays contracting HMOs monthly a flat fee or capitation payment to provide or cover the congressionally mandated package of services. The Secretary has actively encouraged Medicare beneficiaries to enroll in HMOs, and the growth in the number of Medicare beneficiaries enrolled in HMOs accelerated greatly in the 1990's.[1]

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[1] In 1996, 3.8 million Medicare beneficiaries were enrolled in HMOs, more than double the 1.5 million beneficiaries enrolled just three years earlier. McIlrath, *GAO Report, Medicare HMOs*, American Medical News 3 (November 18, 1996); Report

Contrary to the Secretary's suggestion, Medicare HMOs are not analogous to private HMOs. Congress has specified the package of services that Medicare HMOs must provide, *supra* at 3, and the Secretary has elaborated upon these mandates through extensive regulations and manuals. Coverage decisions by Medicare HMOs may be appealed to the Secretary and federal court; in fact, when Congress included risk-based HMO coverage, it expanded HMO beneficiary appeal rights beyond those conferred in the Medicare fee-for-service appeal process to include failure to receive services as well as denials of payment. 42 U.S.C. § 1395mm(c)(5)(B). Extensive and detailed conditions are attached to HMO participation in the Medicare program. 42 C.F.R. §§ 417.1-417.694.

b. The Joint Statement of Facts presented to the district court in this case identified a number of problems with the Medicare HMO program. The six thick volumes of exhibits, which included declarations of named plaintiffs, other beneficiaries and professionals, excerpts from discovery, and studies and investigative reports, show a pattern of denials by HMOs, particularly of certain more costly types of health services.

Beneficiaries' primary remedy for denial of service is the administrative appeal process established by statute and regulations. But the defects of this process impair the relief which it should offer to HMO enrollees who are

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of testimony by Bruce C. Vladek, HCFA Administrator, at February 10, 1995 hearing of the Health Subcommittee of the House Ways and Means Committee, reported at 842 New Developments 5-7, Medicare & Medicaid Guide (CCH).

denied services.[2] HMO notices of denial to beneficiaries are infrequently given and, even when given, are inadequate in content. The hearing process that follows is seriously flawed, both by its extensive delays when services are urgently needed and by the inability of beneficiaries to obtain and supply supporting evidence. As a result, most beneficiaries have no effective remedy when services are denied.

2. In an effort to correct this harmful situation, HMO-enrolled Medicare beneficiaries brought the instant lawsuit, stating four claims. First, the Secretary failed to enforce the obligations of her contracting HMOs to provide congressionally mandated services. Second, the Secretary did not enforce the requirement that her HMOs provide adequate notice when they deny coverage of such health services. Third, the Secretary's failure to provide HMO beneficiaries with a timely appeal when needed health services are denied deprives them of a meaningful hearing. Fourth, in HMO appeals the Secretary should place the burden of proof on the HMO rather than on the beneficiary. After certifying a nationwide class action, the district judge issued summary judgment for beneficiaries on counts two and three of the complaint and for the Secretary on count four. The district court specifically retained jurisdiction to resolve count one.

a. Under two separate analyses, the district court found that, contrary to the Secretary's contention, HMO service denials constituted state action. First, the court

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[2] See generally S. J. Stayn, *Securing Access to Care in HMOs: Toward a Uniform Model of Grievance and Appeal Procedures*, 94 COLUM. L. REV. 1674 (1994).

explained that Medicare HMOs fulfill two separate functions, as insurers and as direct providers of medical care. This case challenges HMOs' performance of Medicare's insurer function; it does not challenge HMOs' performance as providers of medical care. Pet.App. 33a. Courts have consistently found that private contractors fulfilling this insurance function for Medicare act as agents of the Secretary. See *Kraemer v. Heckler*, 737 F.2d 214, 215 (2d Cir. 1984); *Himmler v. Califano*, 611 F.2d 137, 140 (6th Cir. 1979); *Vorster v. Bowen*, 709 F.Supp. 934, 936 (C.D.Cal. 1989); *Fox v. Bowen*, 656 F.Supp. 1236, 1238 (D.Conn. 1986). In the present case, the district court found that "there is nothing unique about the performance of these same duties by HMOs which warrants a contrary finding here." Pet.App. 34a.

Secondly, the court analyzed HMO denials of Medicare services under the criteria set forth in *Catanzano v. Dowling*, 60 F.3d 113 (2d Cir. 1995) (decisions by private home health agencies to deny or reduce the amount of home health care for Medicaid recipients amount to state action triggering due process rights), and in *J.K. v. Dillenberg*, 836 F.Supp. 694 (D.Ariz. 1993) (decisions by private entities that contracted with the state to perform Medicaid mandated behavioral health care duties constituted state action). As in *Catanzano* and *Dillenberg*, the district court found that the criteria for state action apply here. Specifically, the district court found that, with respect to Medicare HMO service denials: (1) the government pays for covered services; (2) the government regulates HMOs' activities as they apply to Medicare beneficiaries, especially benefit coverage determinations; (3) the Secretary issues regulations and directives which cannot be

ignored, and creates the legal framework which governs the activities complained of by beneficiaries; and (4) Medicare beneficiaries appeal HMO service denials directly to the Secretary, who has the power to overturn the HMO decision. Pet.App. 32a-33a.

b. The district court held that Medicare beneficiaries who are denied coverage by contracting HMOs are entitled to due process as are Medicare beneficiaries who are denied coverage in the fee-for-service system. *Id.* at 34a-35b. The court then applied the balancing test set forth by this Court in *Mathews v. Eldridge*, 424 U.S. 319 (1976), to determine the extent of procedural protections required for HMO beneficiaries by due process. Pet.App. 42a-45a. It concluded that the Secretary's current notice and hearing procedures violated due process.

Subsequently, at the court's request, both parties fully briefed their positions regarding the content of the remedial order. Court of Appeals Supplemental Excerpts of Record 1010-1078. The court ordered the parties to enter into binding settlement discussions as to the details of a meaningful notice and appeals process, with the understanding that the Secretary's right to appeal the state action issue would be preserved. When the Secretary took the position that she would not be bound by any settlement agreement, the district court considered the parties' briefing as to the specifics of the injunction and issued its judgment on March 3, 1997. Pet.App. 59a-69a. The court did not strike down Medicare legislation or regulations, but ordered the Secretary to make reforms in five specific areas of its HMO notice and appeals process.

c. On April 30, 1997, two days before the deadline for filing a notice of appeal, the Secretary published a "Final Rule with comment period", which implemented a portion of the court's order. 62 Fed. Reg. 23368 (April 30, 1997). She then requested a stay of the judgment pending appeal, claiming that her new regulations complied with many of the court's procedural requirements, and, significantly, that the other requirements would be addressed by additional regulations in the near future. Def. Motion for Stay Pending Appeal (5/13/97), in Court of Appeals Excerpts of Record (C.A.E.R.) 200. The district court granted the stay based on the Secretary's assurances regarding further compliance: "[T]he entire case may become largely moot if the Secretary's attestations regarding rule changes are true and are implemented without delay." Pet.App. 68a. However, consistent with her regrettably misleading practices throughout this litigation, the Secretary has never issued regulations implementing the rest of the district court's judgment.

d. On August 5, 1997, the Balanced Budget Act of 1997 was enacted, folding Medicare HMOs into a broader Medicare+Choice set of options. The BBA also inserted into the statute some time frames for expedited appeals.

Although the BBA was enacted before the Secretary filed her reply brief in the court of appeals, she declined to discuss the new statute. Instead, she stated without qualification that the BBA provisions "have no effect on the arguments presented in this appeal." Gov't Reply Br. at 10 n.9. Furthermore, at oral argument before the court of appeals on January 13, 1998, the Secretary again disclaimed any effect on this case by the BBA, which had become effective on January 1, 1998.

The BBA provided for expedited appeal in some but not all of the situations addressed by the district court. Unfortunately, neither it nor the Secretary's implementing regulations complied with other important protections included in the judgment below. First, they do not satisfy the five-day timeliness standard for written denial notices.[3] Second, they do not provide for an independent, non-HMO decision-maker in expedited reviews. Third, they fail to provide for urgently needed services to continue pending expedited review. Fourth, they do not implement the congressional mandate for the Secretary's enforcement of HMO contractual conditions.

3. The Ninth Circuit, in a unanimous opinion written by Judge Wiggins, affirmed the district court's decision. Pet.App. 1a-21a. First, the court of appeals held that HMO denials of services to Medicare beneficiaries constitute state action. The court considered each of the factors that point to state action, and stated that, although each factor alone might not be sufficient to establish state action, together they show that the HMOs and the federal government are joint participants in providing Medicare services. Pet.App. 9a-10a. The court distinguished *Blum v. Yaretsky*, 457 U.S. 991 (1982), where physicians made medical treatment decisions based on professional standards, from *Grijalva*, where HMOs make Medicare coverage determinations pursuant to federal law. Pet.App. 11a.

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[3] The Petition incorrectly asserts that the five-day standard is unreasonably rigid. In fact, the judgment carefully provides for extensions of up to sixty days when needed to "make a responsibly considered medical determination." Pet.App. 60a.

The court of appeals then performed its own balancing test under *Mathews v. Eldridge*, and concluded that due process does require the procedural protections for Medicare beneficiaries enrolled in HMOs that were ordered by the district court. Pet.App. 13a.

Finally, the court addressed the Secretary's argument that intervening regulations warranted modifying the district court's injunction. Judge Wiggins noted that the district court has continuing jurisdiction over its injunction and that the Secretary could seek modification through the district court. Pet.App. 20a. As the Secretary had expressly advised the Ninth Circuit that the BBA did not change the issues before it, the court did not address the BBA.

Subsequently, the Secretary filed a Petition for Rehearing With Suggestion For Rehearing En Banc. Her petition was based largely on a reversal in position, namely, that the BBA does affect the issues and relief in this case. The panel unanimously denied the petition, and the court as a whole declined to rehear the case *en banc*. Pet.App. 22a-23a.

REASONS FOR DENYING THE WRIT

A. The Factual And Legal Context Of *Sullivan* Renders The Decision On State Action In That Case Of No Relevance To The Instant Case.

1. The Secretary's reliance on *American Manufacturers Mutual Insurance Co. v. Sullivan*, 119 S.Ct. 977 (1999), as providing grounds to vacate and remand the

decision below is misplaced. In *Sullivan*, this Court held that a private insurer's decision to withhold payment and seek utilization review of whether particular medical treatments were reasonable and necessary is not fairly attributable to the state so as to subject the insurer to the Fourteenth Amendment's constraints. Thus, although the *Sullivan* decision generally discusses this Court's state action jurisprudence, it has no specific relevance to this case and offers no basis for requiring the appeals and district courts to revisit their analyses.

a. Initially, it needs to be emphasized that *Sullivan* does not modify this Court's prior holdings on state action. While enlightening in the application of state action principles to a case under 42 U.S.C. § 1983 involving workers' compensation, *Sullivan* does not alter the analytical framework relied on by the courts below in this case. This Court reaffirmed the traditional two-step approach enunciated in *Lugar v. Edmondson Oil Co.*, 457 U.S. 922, 937 (1982), and reached its conclusion that there was no state action by distinguishing the situation in *Sullivan* from prior state action cases and by carefully parsing the factual contexts in which the different controversies arose. 119 S.Ct. at 985-989. The court of appeals' critique in the instant case is entirely consistent with this Court's long-standing approach, and *Sullivan* makes no change in those parameters previously outlined.[4]

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[4] *Sullivan* also demonstrates that there is no significance to the Secretary's observation that the appellate courts' decisions in *Sullivan* and the instant case failed to include the three principles applicable to the second *Lugar* factor, as set out in *Edmonson v. Leesville Concrete Co.*, 500 U.S. 614, 621-622 (1991). See Pet.Br. 16. The absence of an explicit statement of these

b. It is of paramount importance to the resolution of this Petition, however, that the legal and factual context of *Sullivan* differs dramatically from the instant case. Unlike *Sullivan*, where the state action inquiry focused on private decisions to withhold payment for medical care based on professional standards, with no state obligation to pay or provide benefits, 119 S.Ct. at 986-988, the state action inquiry in the present case turns on HMO coverage determinations which are based on federal law and the governmental obligation to provide benefits.

The Secretary contends that the state action holding below was "predicate[d] . . . largely on the government's regulatory role." Pet.Br. 16. Given this Court's repeated recognition, including in *Sullivan*, 119 S.Ct. at 986, that regulation alone does not convert private action into state action, it is not surprising that the Secretary would seek to frame this case as merely an instance of government regulation. This situation, however, is vastly different from one involving a regulated industry, as the state action finding is here predicated on a comprehensive federal statutory scheme establishing the Medicare program. See *supra* at 2-4.

The structure and operation of the Medicare program, which is detailed at length in the statute, the regulations, and the manuals, are the responsibility of the Secretary to carry out and enforce, and the HMOs which contract with the Secretary play subordinate roles in this

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principles does not necessarily undercut the implicit propriety of the lower courts' analytical approach, regardless of the ultimate outcome of those analyses.

scheme. The Secretary not only sets the benefit entitlement package, coverage and standards for quality, organization, delivery of services, and notice and appeal rights, but exercises a virtual monopsony in its role as the exclusive buyer of beneficiary services. Unlike *Sullivan*, 119 S.Ct. at 988, and *Jackson v. Metropolitan Edison Co.*, 419 U.S. 345, 352-353 (1974), where the state had no obligation to provide service or benefits, in this case the government is obligated to ensure that HMOs provide all federally mandated public benefits. That is the critical difference from the instant case, where the obligation has always attached to the government.

Courts have invariably found state action in the context of government health benefits obligated by statute and provided via a delegation to HMO. In a number of recent decisions courts have explicitly rejected arguments against state action like that made by the Secretary. In *Catanzano*, 60 F.3d at 117-120, state action and consequent due process protections were found in a managed care arrangement for Medicaid benefits. In *Perry v. Chen*, 985 F.Supp. 1197 (D.Ariz. 1996), the court held that managed care organizations contracting with the state's Medicaid program must meet due process requirements when they deny health services to beneficiaries. In *Daniels v. Wadley*, 926 F.Supp. 1305, 1311 (M.D.Tenn. 1996), vacated on this point *sub nom. Daniels v. Menke*, 145 F.3d 1330 (6th Cir. 1998) (table) (vacated for change of circumstances), the district court held that Medicaid-contracting HMOs are state actors and so are subject to due process standards when they deny health services to beneficiaries. Finally, in *J.K. v. Dillenberg*, 836 F.Supp. at 697-699, state action

with constitutional protections was found in private mental health case management services provided under contract with the state Medicaid program.

c. There is no logic in according preferential treatment to HMOs which participate in the Medicare system, when, like fee-for-service providers, they contract with the federal government to carry out federally established coverage decisions and as such are acting as agents. See, *e.g., Heckler v. Community Health Services of Crawford County, Inc.*, 467 U.S. 51, 54, 64 (1984); *Bodimetric Health Services, Inc.*, 903 F.2d at 487; *Kraemer*, 737 F.2d at 215; *Fox*, 656 F.Supp. at 1238. That HMOs participate both in the Medicare program and in the private sector is not a relevant concern. Rather, it is their voluntary participation in the Medicare program and in the provision of Medicare benefits which defines their role as state actors, for, in that context, the HMOs' actions are "fairly attributable to the State." *Sullivan*, 119 S.Ct. at 989.

A finding of no state action in the HMO Medicare context, and the consequent reduction in beneficiary rights, would also create a double and unequal standard for Medicare beneficiaries, depending on whether they were HMO-enrolled or in fee-for-service. The courts below explicitly recognized this unfairness and the fact that there is nothing in the legislative record to indicate a congressional intention to create such a disparate system. See Pet.App. 34a-35a.

Further, the Secretary significantly errs by stating that the court below "conclud[ed] that *medical treatment* decisions by private HMOs concerning their Medicare-

beneficiary members are properly attributed to the federal government." Pet.Br. 16 (emphasis supplied). In fact, the court of appeals' ruling clearly was limited to *coverage decisions* by Medicare HMOs rather than medical judgments. Pet.App. 11a. By contrast, *Sullivan* did not involve coverage determinations but, rather, withholding payment to providers pending resolution of medical treatment disputes, where standards were not established by the state. 119 S.Ct. at 986.[5]

The present case is also quite different from prior cases where the challenged activity turned on judgments made by medical professionals. In *Blum v. Yaretsky*, 457 U.S. at 1008-1009, this Court held that physician treatment decisions do not involve state action. The lower courts here rightly distinguished HMO coverage determinations from the situations in *Blum* and its progeny where no state action was found. Pet.App. 8a-10a, 30a. The Secretary's attempt to insulate herself and her HMOs from accountability by cloaking them in independent professional discretion must fail. See Pet.Br. 17-18 n. 6.

The situation in this case – unlike *Sullivan* – is similar to *West v. Atkins*, 487 U.S. 42 (1988). There, the Court

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[5] The Medicare statute contains a section listing exclusions from its package of covered services; several of the exclusions are services "not reasonable and necessary for . . . [various listed purposes]." S.S.A. § 1862(a)(1). The Secretary has further defined in detail the situations where these exclusions are found. See, *inter alia*, The Medicare Coverage Issues Manual, HCFA-Pub. 6. These Medicare coverage exclusions are not analogous to the Pennsylvania legislation analyzed in *Sullivan*, where medical judgment was a prerequisite to entitlement.

found that a state-contracted physician's delivery of medical treatment to state prison hospital inmates was action fairly attributable to the state, as it had an obligation to provide adequate medical care, it delegated that function, and the private actor voluntarily assumed the obligation by contract. *Id.* at 56. These are the same factors identified by the district and appellate courts below in concluding that there is state action in this situation. See Pet.App. 10a, 32a.

Indeed, the effect of the BBA is to accentuate the Medicare parallel to the circumstances which defined state action in *West*. Under the BBA, when beneficiaries elect to enroll in managed care organizations, they will be "locked in" and dependent on their HMOs to make coverage decisions according to federal law. S.S.A. § 1851(e)(2)(C), added by BBA § 4001, 111 Stat. 281 (misleadingly omitted from Pet.App.; see *id.* at 78a). Consequently, beneficiaries' circumstances will be remarkably similar to those of the inmates in *West*, who also had no alternative to the health care available from the contracting physician – a state actor.

e. The Secretary wrongly discerns significance in her observation that the relationship between Medicare beneficiaries and HMOs is the "product of a private choice." Pet.Br. 17. But it is irrelevant that an HMO's connection to its Medicare beneficiary members resembles the HMO relationship to private health beneficiaries on the issue of choice of plans. As this Court noted in *West*, 487 U.S. at 56 n. 15, whether the role of a putative state actor "parallels one in the private sector is not, by itself, reason to conclude that the former is not acting under color of state law in performing his duties."

The relevant private decision-making at issue in this case is not that of Medicare beneficiaries choosing the HMO route. It is, rather, the voluntary decision of private health plans to participate as contractors in the Medicare program. Consequently, like intermediaries in the traditional fee-for-service Medicare market, they must adhere to the statutory and contractual entitlements to benefits.

2. The lower courts correctly held that principles of due process require the procedural protections ordered in this case for Medicare HMOs. In *Sullivan*, this Court held that the Due Process Clause does not apply to medical benefits under the Pennsylvania workers' compensation law because there is no protected property interest in those benefits. 119 S.Ct. at 990. Here, in direct contrast, this Court, as well as numerous other courts, has long recognized that due process principles apply to the Medicare package of health benefits. *McClure*, 456 U.S. at 198; see also, *e.g.*, *Kraemer*, 737 F.2d at 222; *Gray Panthers*, 652 F.2d at 146; *Martinez*, 472 F.2d at 1121; *Martinez*, 655 F.Supp. 95, 99.

The Secretary complains that, in its due process analysis, the court of appeals did not give substantial weight to agency views, but she misquotes the court's opinion. Pet.Br. 18. Judge Wiggins rejected the Secretary's assertion that *Eldridge* confers "great deference" upon the Secretary's views on the appropriate level of procedural protection, for the simple reason that the language and standard suggested by the Secretary simply do not appear in *Eldridge*. See Pet.App. 13a n.3. In fact, the district judge did give deference to her views on this point, as he conscientiously reviewed both the Secretary's existing procedures and arguments, ruling in her favor on

one of the four counts. Pet.App. 24a *et seq.* In formulating relief, the district court asked the Secretary to file a response to the proposed judgment and then ordered beneficiaries to engage in settlement talks with the Secretary on the remaining issues. District Court Minute Entry of 2/3/97, in C.A.E.R. 199. The court of appeals reviewed the government's interests in a separate section of its opinion, and, even after applying the deference due under *Eldridge*, the court determined that the government had simply failed to advance any convincing argument that the burden on it outweighed the need for additional due process protections.

B. The Secretary's Limited Compliance With The Remedial Order Does Not Moot The Case, And The District Court Has Continuing Jurisdiction To Consider Whether Its Order Should Be Modified.

1. The Secretary's assertion that this case would warrant plenary review absent its alleged similarity with *Sullivan* is unfounded. The decisions below were not nearly so sweeping as to have "declare[d] unconstitutional the Secretary's implementation of a major federal program." Pet.Br. 20. Rather, they simply held that one circumscribed aspect of the Medicare program – appeal rights for HMO beneficiaries – needed improvement to meet judicially recognized standards. Nor did the decisions "constitutionalize" private HMOs. *Id.* HMOs conduct their activities as before, except that appeal procedures for Medicare beneficiaries, which have always been prescribed by the Secretary, are somewhat stricter.

2. Contrary to the Secretary's repeated assertions, the BBA and regulations do not substantially alter the controversy or moot this case. First, the district court's decision did not strike down any particular provisions of the Medicare statute or regulations. Rather, the court focused on the Medicare appeals process as it existed in practice, and ordered the Secretary to improve the process in certain specific ways. Pet.App. 24a-64a. Thus, the BBA did not replace legislation declared invalid by the court, and for that reason many of the decisions cited by the Secretary are not directly applicable to this case. See, *e.g., Lewis v. Continental Bank Corp.*, 494 U.S. 472 (1990); *Bowen v. Kizer*, 485 U.S. 386 (1988); *U.S. Dep't of Treasury v. Galioto*, 477 U.S. 556 (1986); *Princeton Univ. v. Schmid*, 455 U.S. 100 (1982).

Second, the BBA and the new regulations do not satisfy the requirements of the district court's remedial order. The BBA renamed Medicare risk-contracting HMOs "coordinated care plans," grouped them together with some new structures for providing Medicare benefits, and shifted some of the relevant statutory provisions to a new section of the Medicare statute. But neither the statutory framework nor the statutory provisions addressed by the lower courts have changed. Section 1395mm(c)(1) of title 42, which forbids the Secretary from entering into a contract with an HMO unless it meets the statutory requirements and upon which the lower courts relied (Pet.App. 20a, 54a), has *not* been repealed. Section 1395mm(c)(5)(A)'s requirement of meaningful procedures for hearing and resolving grievances between enrollees and the HMO also remains in the statute. See Resp.App. 7.

Although the Secretary describes in glowing detail the salubrious contents of the BBA (Pet.Br. 20-22), she fails to note that many of its procedural provisions deal with matters not raised in this litigation, such as decision-making by qualified medical personnel and the time limitation for non-expedited reconsiderations. Other BBA provisions touted in the Petition simply repeat in statutory form procedural characteristics of the existing system, such as independent review of adverse HMO reconsiderations and subsequent levels of review by ALJs and federal courts. Only one important element of the district court's remedial order is satisfied by the BBA: the requirement that an expedited HMO reconsideration by the HMO be provided within three days (or 72 hours in the BBA) for urgently needed health services. S.S.A. § 1852(g)(3)(B)(iii), added by BBA § 4001, 111 Stat. 294.

However, the other key components of the court order are not met in the BBA and the Secretary's regulations. For example, recognizing the frequent need for prompt medical treatment, the district court required that HMOs make initial determinations within five days of a request for a health care service unless more time is required by the HMO. Pet.App. 60a. The court also required the continuation of on-going and urgently needed acute care services (unless harmful to the enrollee) pending an expedited reconsideration determination. *Id.* at 63a. Finding that existing "notice and informal hearing requirements set forth by statute and regulations are all but ignored," *id.* at 51a, the court required the Secretary to enforce Congress' statutory prohibition against renewing contracts with HMOs that do not comply with federal standards. *Id.* at 54a-55a, 61a,

63a. The BBA does not satisfy these obligations, and the Secretary continues to ignore the bulk of the remedial order.

The Petition asserts that the prohibition against contracting with non-compliant HMOs was mooted by the BBA in its enactment of S.S.A. § 1857, BBA § 4001, 111 Stat. 319. Pet.Br. 24 n.13. While it is true that the new S.S.A. § 1857 uses permissive language in authorizing the Secretary to terminate non-compliant Medicare+Choice organizations generally, the Petition fails to disclose the fact that the BBA did not repeal 42 U.S.C. § 1395mm(c)(1), which mandates non-renewal of Medicare contracts with deficient HMOs. Resp.App. 7. Under the rules of statutory construction, the more specific provision of section 1395mm(c)(1) continues to be controlling in Medicare contracts with HMOs under Medicare+Choice. And where, as here, the intervening legislation and regulations do not resolve many of the underlying controversies or issues, the case is not moot. *Northeastern Fla. Chapter of the Associated Gen. Contractors v. City of Jacksonville*, 508 U.S. 656, 662 (1993) (municipal ordinance conferring minority business preferences voluntarily replaced during appeal did not moot case when replaced by similar statute); *City of Mesquite v. Aladdin's Castle, Inc.*, 455 U.S. 283, 289 (1992) (voluntary compliance did not moot judgment). See also, *e.g.*, *National Independent Coal Operators' Assn. v. Kleppe*, 423 U.S. 388, 393 n.4 (1976) (challenge to validity of regulations regarding administrative hearings not moot where regulation reissued after filing of suit required a hearing if requested); *FEA v. Algonquin SNG, Inc.*, 426 U.S. 548, 558 n.8 (1976) (challenge to administrative imposition of fees on oil imports not mooted by new

federal statute because it did not eliminate one type of fee which respondents sought to enjoin).

3. The Secretary asks the Court to vacate the court of appeals' decision and remand this case to the district court with instructions to vacate its judgment as well and conduct such further proceedings as may be appropriate in light of the BBA and new regulations. Pet.Br. 26. This action is neither necessary nor appropriate for several reasons.

First, it is apparent that the Secretary's regulatory and legislative initiatives were in reaction to the injunction in this case. Even the Secretary should not be allowed to manipulate the judicial process by offering half a loaf after her efforts to evade compliance have failed.

As discussed above, the Secretary advised the court of appeals that it need not consider the effect of the BBA in deciding the appeal. Although that legislation became law in August 1997, before the appeal was fully briefed and argued, the Secretary informed the court that it should not consider its provisions: "[T]hese changes have *no effect* on the arguments presented in this appeal." Gov't Reply Brief at 10 n.9 (emphasis added). Furthermore, although oral argument took place after the January 1, 1998 effective date of the BBA, the Secretary still did not ask the court to consider its effect. Having expressly waived her opportunity to raise this legislation below, the Secretary should not be allowed to use it now to further delay or deny relief to tens of thousands of Medicare beneficiaries.

Second, the relief requested by the Secretary, reconsideration by the district court, may be obtained without the issuance of a writ of certiorari vacating the court of appeals' decision. The district court retained jurisdiction to consider the effects of the procedural changes ordered, Pet.App. 58a, 64a, and, in any event, the Secretary may seek modification in light of the BBA changes on remand to the district court pursuant to Rule 60(b), F.R.Civ.P. At the conclusion of his opinion for the unanimous panel below, Judge Wiggins noted precisely this point:

> The district court has continuing jurisdiction over the modification of the injunction. See *Transgo, Inc. v. Ajac Transmission Parts Corp.*, 768 F.2d 1001, 1030 (9th Cir. 1985) (declining to remand to district court with directions to modify injunction, noting that the party "may apply directly" to the district court for modification in light of post-trial events). The Secretary may move in the district court for a modification of its injunction.

Pet.App. 21a. See also, *e.g.*, *Agostini v. Felton*, 521 U.S. 203 (1997) (discussing standards for a Rule 60(b) motion); *Standard Oil v. U.S.*, 429 U.S. 17 (1976) (unsuccessful appellant may make a Rule 60(b) motion on remand).

Because the intervening legislation and regulations complied only in small part with the lower court's order, this case is far from moot. The court of appeals' opinion directing the Secretary to seek consideration of these subsequent events in the district court was correct. It is not necessary, and certainly not equitable, for this Court to vacate the decisions below merely to allow the Secretary to belatedly raise additional issues. The Secretary,

like all other litigants, should apply to the district court for that relief, rather than ask for this Court's intervention merely because of the fortuitous timing of the petition for a writ of certiorari.

CONCLUSION

For the reasons stated, the Court should deny the petition for a writ of certiorari.

Respectfully submitted,

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Soc. Sec. Act § 1876 [codified 42 U.S.C. § 1395mm] PAYMENTS TO HEALTH MAINTENANCE ORGANIZATIONS AND COMPETITIVE MEDICAL PLANS

Sec. 1876. (a)(1)(A) The Secretary shall annually determine, and shall announce (in a manner intended to provide notice to interested parties) not later than September 7 before the calendar year concerned –

(i) a per capita rate of payment for each class of individuals who are enrolled under this section with an eligible organization which has entered into a risk-sharing contract and who are entitled to benefits under part A and enrolled under part B, and

(ii) a per capita rate of payment for each class of individuals who are so enrolled with such an organization and who are enrolled under part B only.

For purposes of this section, the term "risk-sharing contract" means a contract entered into under subsection (g) and the term "reasonable cost reimbursement contract" means a contract entered into under subsection (h).

(B) The Secretary shall define appropriate classes of members, based on age, disability status, and such other factors as the Secretary determines to be appropriate, so as to ensure actuarial equivalence. The Secretary may add to, modify, or substitute for such classes, if such changes will improve the determination of actuarial equivalence.

(C) The annual per capita rate of payment for each such class shall be equal to 95 percent of the adjusted average per capita cost (as defined in paragraph (4)) for that class.

(D) In the case of an eligible organization with a risk-sharing contract, the Secretary shall make monthly payments in advance and in accordance

with the rate determined under subparagraph (C) and except as provided in subsection (g)(2), to the organization for each individual enrolled with the organization under this section.

(E)(i) The amount of payment under this paragraph may be retroactively adjusted to take into account any difference between the actual number of individuals enrolled in the plan under this section and the number of such individuals estimated to be so enrolled in determining the amount of the advance payment.

(ii)(I) Subject to subclause (II), the Secretary may make retroactive adjustments under clause (i) to take into account individuals enrolled during the period beginning on the date on which the individual enrolls with an eligible organization (which has a risk-sharing contract under this section) under a health benefit plan operated, sponsored, or contributed to by the individual's employer or former employer (or the employer or former employer of the individual's spouse) and ending on the date on which the individual is enrolled in the plan under this section, except that for purposes of making such retroactive adjustments under this clause, such period may not exceed 90 days.

(II) No adjustment may be made under subclause (I) with respect to any individual who does not certify that the organization provided the individual with the explanation described in subsection (c)(3)(E) at the time the individual enrolled with the organization.

(F)(i) At least 45 days before making the announcement under subparagraph (A) for a year

(beginning with the announcement for 1991), the Secretary shall provide for notice to eligible organizations of proposed changes to be made in the methodology or benefit coverage assumptions from the methodology and assumptions used in the previous announcement and shall provide such organizations an opportunity to comment on such proposed changes.

(ii) In each announcement made under subparagraph (A) for a year (beginning with the announcement for 1991), the Secretary shall include an explanation of the assumptions (including any benefit coverage assumptions) and changes in methodology used in the announcement in sufficient detail so that eligible organizations can compute per capita rates of payment for classes of individuals located in each county (or equivalent area) which is in whole or in part within the service area of such an organization.

(2) With respect to any eligible organization which has entered into a reasonable cost reimbursement contract, payments shall be made to such plan in accordance with subsection (h)(2) rather than paragraph (1).

(3) Subject to subsections (c)(2)(B)(ii) and (c)(7), payments under a contract to an eligible organization under paragraph (1) or (2) shall be instead of the amounts which (in the absence of the contract) would be otherwise payable, pursuant to sections 1814(b) and 1833(a), for services furnished by or through the organization to individuals enrolled with the organization under this section.

(4) For purposes of this section, the term "adjusted average per capita cost" means the average per capita amount that the Secretary estimates in advance (on the

basis of actual experience, or retrospective actuarial equivalent based upon an adequate sample and other information and data, in a geographic area served by an eligible organization or in a similar area, with appropriate adjustments to assure actuarial equivalence) would be payable in any contract year for services covered under parts A and B, or part B only, and types of expenses otherwise reimbursable under parts A and B, or part B only (including administrative costs incurred by organizations described in sections 1816 and 1842), if the services were to be furnished by other than an eligible organization or, in the case of services covered only under section 1861(s)(2)(H), if the services were to be furnished by a physician or as an incident to a physician's service.

(5) The payment to an eligible organization under this section for individuals enrolled under this section with the organization and entitled to benefits under part A and enrolled under part B of this subchapter shall be made from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund. The portion of that payment to the organization for a month to be paid by each trust fund shall be determined as follows:

(A) In regard to expenditures by eligible organizations having risk-sharing contracts, the allocation shall be determined each year by the Secretary based on the relative weight that benefits from each fund contribute to the adjusted average per capita cost.

(B) In regard to expenditures by eligible organizations operating under a reasonable cost reimbursement contract, the initial allocation shall be based on

the plan's most recent budget, such allocation to be adjusted, as needed, after cost settlement to reflect the distribution of actual expenditures.

The remainder of that payment shall be paid by the former trust fund.

(6) Subject to subsections (c)(2)(B)(ii) and (c)(7), if an individual is enrolled under this section with an eligible organization having a risk-sharing contract, only the eligible organization shall be entitled to receive payments from the Secretary under this title for services furnished to the individual.

(b) For purposes of this section, the term "eligible organization" means a public or private entity (which may be a health maintenance organization or a competitive medical plan), organized under the laws of any State, which –

(1) is a qualified health maintenance organization (as defined in section 1310(d) of the Public Health Service Act), or

(2) meets the following requirements:

(A) The entity provides to enrolled members at least the following health care services:

(i) Physicians' services performed by physicians (as defined in section 1861(r)(1)).

(ii) Inpatient hospital services.

(iii) Laboratory, X-ray, emergency, and preventive services.

(iv) Out-of-area coverage.

(B) The entity is compensated (except for deductibles, coinsurance, and copayments) for the provision of health care services to enrolled members by a payment which is paid on a periodic basis without regard to the date the health care services are provided and which is fixed without regard to the frequency, extent, or kind of health care service actually provided to a member.

(C) The entity provides physicians' services primarily (i) directly through physicians who are either employees or partners of such organization, or (ii) through contracts with individual physicians or one or more groups of physicians (organized on a group practice or individual practice basis).

(D) The entity assumes full financial risk on a prospective basis for the provision of the health care services listed in subparagraph (A), except that such entity may –

(i) obtain insurance or make other arrangements for the cost of providing to any enrolled member health care services listed in subparagraph (A) the aggregate value of which exceeds $5,000 in any year,

(ii) obtain insurance or make other arrangements for the cost of health care service listed in subparagraph (A) provided to its enrolled members other than through the entity because medical necessity required their provision before they could be secured through the entity,

(iii) obtain insurance or make other arrangements for not more than 90 percent of the amount by which its costs for any of its fiscal years exceed 115 percent of its income for such fiscal year, and

(iv) make arrangements with physicians or other health professionals, health care institutions, or any combination of such individuals or institutions to assume all or part of the financial risk on a prospective basis for the provision of basic health services by the physicians or other health professionals or through the institutions.

(E) The entity has made adequate provision against the risk of insolvency, which provision is satisfactory to the Secretary.

Paragraph (2)(A)(ii) shall not apply to an entity which had contracted with a single State agency administering a State plan approved under title XIX of this chapter for the provision of services (other than inpatient hospital services) to individuals eligible for such services under such State plan on a prepaid risk basis prior to 1970.

(c)(1) The Secretary may not enter into a contract under this section with an eligible organization unless it meets the requirements of this subsection and subsection (e) with respect to members enrolled under this section.

(2)(A) The organization must provide to members enrolled under this section, through providers and other persons that meet the applicable requirements of this title and part A of title XI –

(i) only those services covered under parts A and B of this title, for those members entitled to

benefits under part A and enrolled under part B, or

(ii) only those services covered under part B, for those members enrolled only under such part,

which are available to individuals residing in the geographic area served by the organization, except that (I) the organization may provide such members with such additional health care services as the members may elect, at their option, to have covered, and (II) in the case of an organization with a risk-sharing contract, the organization may provide such members with such additional health care services as the Secretary may approve. The Secretary shall approve any such additional health care services which the organization proposes to offer to such members, unless the Secretary determines that including such additional services will substantially discourage enrollment by covered individuals with the organization.

(B) If there is a national coverage determination made in the period beginning on the date of an announcement under subsection (a)(1)(A) and ending on the date of the next announcement under such subsection that the Secretary projects will result in a significant change in the costs to the organization of providing the benefits that are the subject of such national coverage determination and that was not incorporated in the determination of the per capita rate of payment included in the announcement made at the beginning of such period –

(i) such determination shall not apply to risk-sharing contracts under this section until the first contract year that begins after the end of such period; and

(ii) if such coverage determination provides for coverage of additional benefits or under additional circumstances, subsection (a)(3) shall not apply to payment for such additional benefits or benefits provided under such additional circumstances until the first contract year that begins after the end of such period,

unless otherwise required by law.

(3)(A)(i) Each eligible organization must have an open enrollment period, for the enrollment of individuals under this section, of at least 30 days duration every year and including the period or periods specified under clause (ii), and must provide that at any time during which enrollments are accepted, the organization will accept up to the limits of its capacity (as determined by the Secretary) and without restrictions, except as may be authorized in regulations, individuals who are eligible to enroll under subsection (d) in the order in which they apply for enrollment, unless to do so would result in failure to meet the requirements of subsection (f) or would result in the enrollment of enrollees substantially nonrepresentative, as determined in accordance with regulations of the Secretary, of the population in the geographic area served by the organization.

(ii)(I) If a risk-sharing contract under this section is not renewed or is otherwise terminated, eligible organizations with risk-sharing contracts under this section and serving a part of the same service area as under the terminated contract are required to have an open enrollment period for individuals who were enrolled under the terminated contract as of the date of notice of such termination. If a risk-sharing contract under this section is

renewed in a manner that discontinues coverage for individuals residing in part of the service area, eligible organizations with risk-sharing contracts under this section and enrolling individuals residing in that part of the service area are required to have an open enrollment period for individuals residing in the part of the service area who were enrolled under the contract as of the date of notice of such discontinued coverage.

(II) The open enrollment periods required under subclause (I) shall be for 30 days and shall begin 30 days after the date that the Secretary provides notice of such requirement.

(III) Enrollment under this clause shall be effective 30 days after the end of the open enrollment period, or, if the Secretary determines that such date is not feasible, such other date as the Secretary specifies.

(B) An individual may enroll under this section with an eligible organization in such manner as may be prescribed in regulations and may terminate his enrollment with the eligible organization as of the beginning of the first calendar month following the date on which the request is made for such termination (or, in the case of financial insolvency of the organization, as may be prescribed by regulations) or, in the case of such an organization with a reasonable cost reimbursement contract, as may be prescribed by regulations.

(C) The Secretary may prescribe the procedures and conditions under which an eligible organization that has entered into a contract with the Secretary under this subsection may inform individuals eligible to enroll

under this section with the organization about the organization, or may enroll such individuals with the organization. No brochures, application forms, or other promotional or informational material may be distributed by an organization to (or for the use of) individuals eligible to enroll with the organization under this section unless (i) at least 45 days before its distribution, the organization has submitted the material to the Secretary for review and (ii) the Secretary has not disapproved the distribution of the material. The Secretary shall review all such material submitted and shall disapprove such material if the Secretary determines, in the Secretary's discretion, that the material is materially inaccurate or misleading or otherwise makes a material misrepresentation.

(D) The organization must provide assurances to the Secretary that it will not expel or refuse to re-enroll any such individual because of the individual's health status or requirements for health care services, and that it will notify each such individual of such fact at the time of the individual's enrollment.

(E) Each eligible organization shall provide each enrollee, at the time of enrollment and not less frequently than annually thereafter, an explanation of the enrollee's rights under this section, including an explanation of –

(i) the enrollee's rights to benefits from the organization,

(ii) the restrictions on payments under this title for services furnished other than by or through the organization,

(iii) out-of-area coverage provided by the organization,

(iv) the organization's coverage of emergency services and urgently needed care, and

(v) appeal rights of enrollees.

(F) Each eligible organization that provides items and services pursuant to a contract under this section shall provide assurances to the Secretary that in the event the organization ceases to provide such items and services, the organization shall provide or arrange for supplemental coverage of benefits under this title related to a pre-existing condition with respect to any exclusion period, to all individuals enrolled with the entity who receive benefits under this title, for the lesser of six months or the duration of such period.

(G)(i) Each eligible organization having a risk-sharing contract under this section shall notify individuals eligible to enroll with the organization under this section and individuals enrolled with the organization under this section that –

(I) the organization is authorized by law to terminate or refuse to renew the contract, and

(II) termination or nonrenewal of the contract may result in termination of the enrollments of individuals enrolled with the organization under this section.

(ii) The notice required by clause (i) shall be included in –

(I) any marketing materials described in subparagraph (C) that are distributed by an eligible

organization to individuals eligible to enroll under this section with the organization, and

(II) any explanation provided to enrollees by the organization pursuant to subparagraph (E).

(4) The organization must –

(A) make the services described in paragraph (2) (and such other health care services as such individuals have contracted for) (i) available and accessible to each such individual, within the area served by the organization, with reasonable promptness and in a manner which assures continuity, and (ii) when medically necessary, available and accessible twenty-four hours a day and seven days a week, and

(B) provide for reimbursement with respect to services which are described in subparagraph (A) and which are provided to such an individual other than through the organization, if (i) the services were medically necessary and immediately required because of an unforeseen illness, injury, or condition and (ii) it was not reasonable given the circumstances to obtain the services through the organization.

(5)(A) The organization must provide meaningful procedures for hearing and resolving grievances between the organization (including any entity or individual through which the organization provides health care services) and members enrolled with the organization under this section.

(B) A member enrolled with an eligible organization under this section who is dissatisfied by reason of his failure to receive any health service to which he believes he is entitled and at no greater charge than he believes he is required to pay is entitled, if the amount in controversy is $100 or more, to a hearing before the Secretary to the

same extent as is provided in section 205(b), and in any such hearing the Secretary shall make the eligible organization a party. If the amount in controversy is $1,000 or more, the individual or eligible organization shall, upon notifying the other party, be entitled to judicial review of the Secretary's final decision as provided in section 205(g), and both the individual and the eligible organization shall be entitled to be parties to that judicial review. In applying sections 205(b) and 205(g) as provided in this subparagraph, and in applying section 205(l) thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

(6) The organization must have arrangements, established in accordance with regulations of the Secretary, for an ongoing quality assurance program for health care services it provides to such individuals, which program (A) stresses health outcomes and (B) provides review by physicians and other health care professionals of the process followed in the provision of such health care services.

(7) A risk-sharing contract under this section shall provide that in the case of an individual who is receiving inpatient hospital services from a subsection (d) hospital (as defined in section 1886(d)(1)(B)) as of the effective date of the individual's –

(A) enrollment with an eligible organization under this section –

(i) payment for such services until the date of the individual's discharge shall be made

under this title as if the individual were not enrolled with the organization,

(ii) the organization shall not be financially responsible for payment for such services until the date after the date of the individual's discharge, and

(iii) the organization shall nonetheless be paid the full amount otherwise payable to the organization under this section; or

(B) termination of enrollment with an eligible organization under this section –

(i) the organization shall be financially responsible for payment for such services after such date and until the date of the individual's discharge,

(ii) payment for such services during the stay shall not be made under section 1886(d), and

(iii) the organization shall not receive any payment with respect to the individual under this section during the period the individual is not enrolled.

In the case of an individual's termination of enrollment, the organization shall provide the individual with a copy of the written request for termination of enrollment and a written explanation of the period (ending on the effective date of the termination) during which the individual continues to be enrolled with the organization and may not receive benefits under this title other than through the organization.

(8) A contract under this section shall provide that the eligible organization shall meet the requirement of

section 1866(f) (relating to maintaining written policies and procedures respecting advance directives).

(d) Subject to the provisions of subsection (c)(3), every individual entitled to benefits under part A and enrolled under part B or enrolled under part B only (other than an individual medically determined to have end-stage renal disease) shall be eligible to enroll under this section with any eligible organization with which the Secretary has entered into a contract under this section and which serves the geographic area in which the individual resides.

(e)(1) In no case may –

(A) the portion of an eligible organization's premium rate and the actuarial value of its deductibles, coinsurance, and copayments charged (with respect to services covered under parts A and B) to individuals who are enrolled under this section with the organization and who are entitled to benefits under part A and enrolled under part B, or

(B) the portion of its premium rate and the actuarial value of its deductibles, coinsurance, and copayments charged (with respect to services covered under part B) to individuals who are enrolled under this section with the organization and enrolled under part B only

exceed the actuarial value of the coinsurance and deductibles that would be applicable on the average to individuals enrolled under this section with the organization (or, if the Secretary finds that adequate data are not available to determine that actuarial value, the actuarial value of the coinsurance and deductibles applicable on the average to individuals in the area, in the State, or in the

United States, eligible to enroll under this section with the organization, or other appropriate data) and entitled to benefits under part A and enrolled under part B, or enrolled under part B only, respectively, if they were not members of an eligible organization.

(2) If the eligible organization provides to its members enrolled under this section services in addition to services covered under parts A and B of this title, election of coverage for such additional services (unless such services have been approved by the Secretary under subsection (c)(2)) shall be optional for such members and such organization shall furnish such members with information on the portion of its premium rate or other charges applicable to such additional services. In no case may the sum of –

(A) the portion of such organization's premium rate charged, with respect to such additional services, to members enrolled under this section, and

(B) the actuarial value of its deductibles, coinsurance, and copayments charged, with respect to such services to such members

exceed the adjusted community rate for such services.

(3) For purposes of this section, the term "adjusted community rate" for a service or services means, at the election of an eligible organization, either –

(A) the rate of payment for that service or services which the Secretary annually determines would apply to a member enrolled under this section with an eligible organization if the rate of payment were determined under a "community rating system" (as defined in section 1302(8) of the Public Health Service Act, other than subparagraph (C)), or

(B) such portion of the weighted aggregate premium, which the Secretary annually estimates would apply to a member enrolled under this section with the eligible organization, as the Secretary annually estimates is attributable to that service or services,

but adjusted for differences between the utilization characteristics of the members enrolled with the eligible organization under this section and the utilization characteristics of the other members of the organization (or, if the Secretary finds that adequate data are not available to adjust for those differences, the differences between the utilization characteristics of members in other eligible organizations, or individuals in the area, in the State, or in the United States, eligible to enroll under this section with an eligible organization and the utilization characteristics of the rest of the population in the area, in the State, or in the United States, respectively).

(4) Notwithstanding any other provision of law, the eligible organization may (in the case of the provision of services to a member enrolled under this section for an illness or injury for which the member is entitled to benefits under a workmen's compensation law or plan of the United States or a State, under an automobile or liability insurance policy or plan, including a self-insured plan, or under no fault insurance) charge or authorize the provider of such services to charge, in accordance with the charges allowed under such law or policy –

(A) the insurance carrier, employer, or other entity which under such law, plan, or policy is to pay for the provision of such services, or

(B) such member to the extent that the member has been paid under such law, plan, or policy for such services.

(f)(1) For contract periods beginning before January 1, 1999, each eligible organization with which the Secretary enters into a contract under this section shall have, for the duration of such contract, an enrolled membership at least one-half of which consists of individuals who are not entitled to benefits under this title.

(2) Subject to paragraph (4), The Secretary may modify or waive the requirement imposed by paragraph (1) –

(A) to the extent that more than 50 percent of the population of the area served by the organization consists of individuals who are entitled to benefits under this title or under a State plan approved under title XIX, or

(B) in the case of an eligible organization that is owned and operated by a governmental entity, only with respect to a period of three years beginning on the date the organization first enters into a contract under this section, and only if the organization has taken and is making reasonable efforts to enroll individuals who are not entitled to benefits under this title or under a State plan approved under title XIX.

(3) If the Secretary determines that an eligible organization has failed to comply with the requirements of this subsection, the Secretary may provide for the suspension of enrollment of individuals under this section or of payment to the organization under this section for individuals newly enrolled with the organization, after the

date the Secretary notifies the organization of such non-compliance.

(4) Effective for contract periods beginning after December 31, 1996, the Secretary may waive or modify the requirement imposed by paragraph (1) to the extent the Secretary finds that it is in the public interest.

(g)(1) The Secretary may enter a risk-sharing contract with any eligible organization, as defined in subsection (b), which has at least 5,000 members, except that the Secretary may enter into such a contract with an eligible organization that has fewer members if the organization primarily serves members residing outside of urbanized areas.

(2) Each risk-sharing contract shall provide that –

(A) if the adjusted community rate, as defined in subsection (e)(3), for services under parts A and B (as reduced for the actuarial value of the coinsurance and deductibles under those parts) for members enrolled under this section with the organization and entitled to benefits under part A and enrolled in part B, or

(B) if the adjusted community rate for services under part B (as reduced for the actuarial value of the coinsurance and deductibles under that part) for members enrolled under this section with the organization and entitled to benefits under part B only is less than the average of the per capita rates to benefits under part B only

is less than the average of the per capita rates of payment to be made under subsection (a)(1) at the beginning of an annual contract period for members enrolled under this section with the organization and entitled to benefits

under part A and enrolled in part B, or enrolled in part B only, respectively, the eligible organization shall provide to members enrolled under a risk-sharing contract under this section with the organization and entitled to benefits under part A and enrolled in part B, or enrolled in part B only, respectively, the additional benefits described in paragraph (3) which are selected by the eligible organization and which the Secretary finds are at least equal in value to the difference between that average per capita payment and the adjusted community rate (as so reduced); except that this paragraph shall not apply with respect to any organization which elects to receive a lesser payment to the extent that there is no longer a difference between the average per capita payment and adjusted community rate (as so reduced) and except that an organization (with the approval of the Secretary) may provide that a part of the value of such additional benefits be withheld and reserved by the Secretary as provided in paragraph (5). If the Secretary finds that there is insufficient enrollment experience to determine an average of the per capita rates of payment to be made under subsection (a)(1) at the beginning of a contract period, the Secretary may determine such an average based on the enrollment experience of other contracts entered into under this section.

(3) The additional benefits referred to in paragraph (2) are –

(A) the reduction of the premium rate or other charges made with respect to services furnished by the organization to members enrolled under this section, or

(B) the provision of additional health benefits,

or both.

(4) [Repealed.]

(5) An organization having a risk-sharing contract under this section may (with the approval of the Secretary) provide that a part of the value of additional benefits otherwise required to be provided by reason of paragraph (2) be withheld and reserved in the Federal Hospital Insurance Trust Fund and in the Federal Supplementary Medical Insurance Trust Fund (in such proportions as the Secretary determines to be appropriate) by the Secretary for subsequent annual contract periods, to the extent required to stabilize and prevent undue fluctuations in the additional benefits offered in those subsequent periods by the organization in accordance with paragraph (3). Any of such value of additional benefits which is not provided to members of the organization in accordance with paragraph (3) prior to the end of such period, shall revert for the use of such trust funds.

(6)(A) A risk-sharing contract under this section shall require the eligible organization to provide prompt payment (consistent with the provisions of sections 1816(c)(2) and 1842(c)(2)) of claims submitted for services and supplies furnished to individuals pursuant to such contract, if the services or supplies are not furnished under a contract between the organization and the provider or supplier.

(B) In the case of an eligible organization which the Secretary determines, after notice and opportunity for a hearing, has failed to make payments of amounts in compliance with subparagraph (A), the Secretary may provide for direct payment of the amounts owed to providers and suppliers for such covered services furnished to individuals enrolled under this section under the contract. If the Secretary provides for such direct payments, the Secretary shall provide for an appropriate reduction in the amount of payments otherwise made to the organization under this section to reflect the amount of the Secretary's payments (and costs incurred by the Secretary in making such payments).

(h)(1) If –

(A) the Secretary is not satisfied that an eligible organization has the capacity to bear the risk of potential losses under a risk-sharing contract under this section, or

(B) the eligible organization so elects or has an insufficient number of members to be eligible to enter into a risk-sharing contract under subsection (g)(1),

the Secretary may, if he is otherwise satisfied that the eligible organization is able to perform its contractual obligations effectively and efficiently, enter into a contract with such organization pursuant to which such organization is reimbursed on the basis of its reasonable cost (as defined in section 1861(v)) in the manner prescribed in paragraph (3).

(2) A reasonable cost reimbursement contract under this subsection may, at the option of such organization, provide that the Secretary –

(A) will reimburse hospitals and skilled nursing facilities either for the reasonable cost (as determined under section 1861(v)) or for payment amounts determined in accordance with section 1886, as applicable, of services furnished to individuals enrolled with such organization pursuant to subsection (d), and

(B) will deduct the amount of such reimbursement from payment which would otherwise be made to such organization.

If such an eligible organization pays a hospital or skilled nursing facility directly, the amount paid shall not exceed the reasonable cost of the services (as determined under section 1861(v)) or the amount determined under section 1886, as applicable, unless such organization demonstrates to the satisfaction of the Secretary that such excess payments are justified on the basis of advantages gained by the organization.

(3) Payments made to an organization with a reasonable cost reimbursement contract shall be subject to appropriate retroactive corrective adjustment at the end of each contract year so as to assure that such organization is paid for the reasonable cost actually incurred (excluding any part of incurred cost found to be unnecessary in the efficient delivery of health services) or the amounts otherwise determined under section 1886 for the types of expenses otherwise reimbursable under this title for providing services covered under this title to individuals described in subsection (a)(1).

(4) Any reasonable cost reimbursement contract with an eligible organization under this subsection shall provide that the Secretary shall require, at such time following the expiration of each accounting period of the eligible organization (and in such form and in such detail) as he may prescribe –

(A) that the organization report to him in an independently certified financial statement its per capita incurred cost based on the types of components of expenses otherwise reimbursable under this title for providing services described in subsection (a)(1), including therein, in accordance with accounting procedures prescribed by the Secretary, its methods of allocating costs between individuals enrolled under this section and other individuals enrolled with such organization;

(B) that failure to report such information as may be required may be deemed to constitute evidence of likely overpayment on the basis of which appropriate collection action may be taken;

(C) that in any case in which an eligible organization is related to another organization by common ownership or control, a consolidated financial statement shall be filed and that the allowable costs for such organization may not include costs for the types of expense otherwise reimbursable under this title, in excess of those which would be determined to be reasonable in accordance with regulations (providing for limiting reimbursement to costs rather than charges to the eligible organization by related organizations and owners) issued by the Secretary; and

(D) that in any case in which compensation is paid by an eligible organization substantially in excess of what is normally paid for similar services by similar practitioners (regardless of method of

compensation), such compensation may as appropriate be considered to constitute a distribution of profits.

(5)(A) After the date of the enactment of this paragraph, the Secretary may not enter into a reasonable cost reimbursement contract under this subsection (if the contract is not in effect as of such date), except for a contract with an eligible organization which, immediately previous to entering into such contract, had an agreement in effect under section 1833(a)(1)(A).

(B) The Secretary may not extend or renew a reasonable cost reimbursement contract under this subsection for any period beyond December 31, 2002.

(i)(1) Each contract under this section shall be for a term of at least one year, as determined by the Secretary, and may be made automatically renewable from term to term in the absence of notice by either party of intention to terminate at the end of the current term; except that in accordance with procedures established under paragraph (9), the Secretary may at any time terminate any such contract or may impose the intermediate sanctions described in paragraph (6)(B) or (6)(C) (whichever is applicable) on the eligible organization if the Secretary determines that the organization –

(A) has failed substantially to carry out the contract;

(B) is carrying out the contract in a manner substantially inconsistent with the efficient and effective administration of this section; or

(C) no longer substantially meets the applicable conditions of subsections (b), (c), (e), and (f).

(2) The effective date of any contract executed pursuant to this section shall be specified in the contract.

(3) Each contract under this section –

(A) shall provide that the Secretary, or any person or organization designated by him –

(i) shall have the right to inspect or otherwise evaluate (I) the quality, appropriateness, and timeliness of services performed under the contract and (II) the facilities of the organization when there is reasonable evidence of some need for such inspection, and

(ii) shall have the right to audit and inspect any books and records of the eligible organization that pertain (I) to the ability of the organization to bear the risk of potential financial losses, or (II) to services performed or determinations of amounts payable under the contract;

(B) shall require the organization with a risk-sharing contract to provide (and pay for) written notice in advance of the contract's termination, as well as a description of alternatives for obtaining benefits under this title, to each individual enrolled under this section with the organization; and

(C)(i) shall require the organization to comply with subsections (a) and (c) of section 1318 of the Public Health Service Act (relating to disclosure of certain financial information) and with the requirement of section 1301(c)(8) of such Act (relating to liability arrangements to protect members);

(ii) shall require the organization to provide and supply information (described in section 1866(b)(2)(C)(ii))) in the manner such information is required to be provided or supplied under that section;

(iii) shall require the organization to notify the Secretary of loans and other special financial arrangements which are made between the organization and subcontractors, affiliates, and related parties; and

(D) shall contain such other terms and conditions not inconsistent with this section (including requiring the organization to provide the Secretary with such information) as the Secretary may find necessary and appropriate.

(4) The Secretary may not enter into a risk-sharing contract with an eligible organization if a previous risk-sharing contract with that organization under this section was terminated at the request of the organization within the preceding five-year period, except in circumstances which warrant special consideration, as determined by the Secretary.

(5) The authority vested in the Secretary by this section may be performed without regard to such provisions of law or regulations relating to the making, performance, amendment, or modification of contracts of the United States as the Secretary may determine to be inconsistent with the furtherance of the purpose of this title.

(6)(A) If the Secretary determines that an eligible organization with a contract under this section –

(i) fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual;

(ii) imposes premiums on individuals enrolled under this section in excess of the premiums permitted;

(iii) acts to expel or to refuse to re-enroll an individual in violation of the provisions of this section;

(iv) engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this section) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services;

(v) misrepresents or falsifies information that is furnished –

(I) to the Secretary under this section, or

(II) to an individual or to any other entity under this section;

(vi) fails to comply with the requirements of subsection (g)(6)(A) or paragraph (8); or

(vii) in the case of a risk-sharing contract, employs or contracts with any individual or entity that is excluded from participation under this title under section 1128 or 1128A for the provision of health care, utilization review, medical social work, or administrative services or employs or contracts with any entity for the provision (directly or indirectly) through such an excluded individual or entity of such services;

the Secretary may provide, in addition to any other remedies authorized by law, for any of the remedies described in subparagraph (B).

(B) The remedies described in this subparagraph are –

(i) civil money penalties of not more than $25,000 for each determination under subparagraph (A) or, with respect to a determination under clause (iv) or (v)(I), of not more than $100,000 for each such determination, plus, with respect to a determination under subparagraph (A)(ii), double the excess amount charged in violation of such subparagraph (and the excess amount charged shall be deducted from the penalty and returned to the individual concerned), and plus, with respect to a determination under subparagraph (A)(iv), $15,000 for each individual not enrolled as a result of the practice involved,

(ii) suspension of enrollment of individuals under this section after the date the Secretary notifies the organization of a determination under subparagraph (A) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur, or

(iii) suspension of payment to the organization under this section for individuals enrolled after the date the Secretary notifies the organization of a determination under subparagraph (A) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur.

(C) In the case of an eligible organization for which the Secretary makes a determination under paragraph (1), the basis of which is not described in subparagraph (A), the Secretary may apply the following intermediate sanctions:

(i) Civil money penalties of not more than $25,000 for each determination under paragraph

(1) if the deficiency that is the basis of the determination has directly adversely affected (or has the substantial likelihood of adversely affecting) an individual covered under the organization's contract.

(ii) Civil money penalties of not more than $10,000 for each week beginning after the initiation of procedures by the Secretary under paragraph (9) during which the deficiency that is the basis of a determination under paragraph (1) exists.

(iii) Suspension of enrollment of individuals under this section after the date the Secretary notifies the organization of a determination under paragraph (1) and until the Secretary is satisfied that the deficiency that is the basis for the determination has been corrected and is not likely to recur.

(D) The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under subparagraph (B)(i) or (C)(i) in the same manner as such provisions apply to a civil money penalty or proceeding under section 1128A(a).

(7)(A) Each risk-sharing contract with an eligible organization under this section shall provide that the organization will maintain a written agreement with a utilization and quality control peer review organization (which has a contract with the Secretary under part B of title XI of this chapter for the area in which the eligible organization is located) or with an entity selected by the Secretary under section 1154(a)(4)(C) under which the review organization will perform functions under section 1154(a)(4)(B) and section 1154(a)(14) (other than those performed under contracts described in section

1866(a)(I)(F)) with respect to services, furnished by the eligible organization, for which payment may be made under this title.

(B) For purposes of payment under this title, the cost of such agreement to the eligible organization shall be considered a cost incurred by a provider of services in providing covered services under this title and shall be paid directly by the Secretary to the review organization on behalf of such eligible organization in accordance with a schedule established by the Secretary.

(C) Such payments –

(i) shall be transferred in appropriate proportions from the Federal Hospital Insurance Trust Fund and from the Supplementary Medical Insurance Trust Fund, without regard to amounts appropriated in advance in appropriation Acts, in the same manner as transfers are made for payment for services provided directly to beneficiaries, and

(ii) shall not be less in the aggregate for such organizations for a fiscal year than the amounts the Secretary determines to be sufficient to cover the costs of such organizations conducting activities described in subparagraph (A) with respect to such eligible organizations under part B of title XI.

(8)(A) Each contract with an eligible organization under this section shall provide that the organization may not operate any physician incentive plan (as defined in subparagraph (B)) unless the following requirements are met:

(i) No specific payment is made directly or indirectly under the plan to a physician or physician group as an inducement to reduce or limit medically necessary services provided with respect to a specific individual enrolled with the organization.

(ii) If the plan places a physician or physician group at substantial financial risk (as determined by the Secretary) for services not provided by the physician or physician group, the organization –

(I) provides stop-loss protection for the physician or group that is adequate and appropriate, based on standards developed by the Secretary that take into account the number of physicians placed at such substantial financial risk in the group or under the plan and the number of individuals enrolled with the organization who receive services from the physician or the physician group, and

(II) conducts periodic surveys of both individuals enrolled and individuals previously enrolled with the organization to determine the degree of access of such individuals to services provided by the organization and satisfaction with the quality of such services.

(iii) The organization provides the Secretary with descriptive information regarding the plan, sufficient to permit the Secretary to determine whether the plan is in compliance with the requirements of this subparagraph.

(B) In this paragraph, the term "physician incentive plan" means any compensation arrangement between an eligible organization and a physician or physician group that may directly or

indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled with the organization.

(9) The Secretary may terminate a contract with an eligible organization under this section or may impose the intermediate sanctions described in paragraph (6) on the organization in accordance with formal investigation and compliance procedures established by the Secretary under which –

(A) the Secretary first provides the organization with the reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis of the Secretary's determination under paragraph (1) and the organization fails to develop or implement such a plan;

(B) in deciding whether to impose sanctions, the Secretary considers aggravating factors such as whether an organization has a history of deficiencies or has not taken action to correct deficiencies the Secretary has brought to the organization's attention;

(C) there are no unreasonable or unnecessary delays between the finding of a deficiency and the imposition of sanctions; and

(D) the Secretary provides the organization with reasonable notice and opportunity for hearing (including the right to appeal an initial decision) before imposing any sanction or terminating the contract.

(j)(1)(A) In the case of physicians' services or renal dialysis services described in paragraph (2) which are furnished by a participating physician or provider of services or renal dialysis facility to an individual enrolled with an eligible organization under this section and

enrolled under part B, the applicable participation agreement is deemed to provide that the physician or provider of services or renal dialysis facility will accept as payment in full from the eligible organization the amount that would be payable to the physician or provider of services or renal dialysis facility under part B and from the individual under such part, if the individual were not enrolled with an eligible organization under this section.

(B) In the case of physicians' services described in paragraph (2) which are furnished by a nonparticipating physician, the limitations on actual charges for such services otherwise applicable under part B (to services furnished by individuals not enrolled with an eligible organization under this section) shall apply in the same manner as such limitations apply to services furnished to individuals not enrolled with such an organization.

(2) The physicians' services or renal dialysis services described in this paragraph are physicians' services or renal dialysis services which are furnished to an enrollee of an eligible organization under this section by a physician, provider of services, or renal dialysis facility who is not under a contract with the organization.

(k)(1) Except as provided in paragraph (2) –

(A) on or after the date standards for Medicare +Choice organizations and plans are first established under section 1856(b)(1), the Secretary shall not enter into any risksharing contract under this section with an eligible organization; and

(B) for any contract year beginning on or after January 1, 1999, the Secretary shall not renew any such contract.

(2) An individual who is enrolled in part B only and is enrolled in an eligible organization with a risk-

sharing contract under this section on December 31, 1998, may continue enrollment in such organization in accordance with regulations described in section 1856(b)(1).

(3) Notwithstanding subsection (a), the Secretary shall provide that payment amounts under risk-sharing contracts under this section for months in a year (beginning with January 1998) shall be computed –

(A) with respect to individuals entitled to benefits under both parts A and B, by substituting payment rates under section 1853(a) for the payment rates otherwise established under section 1876(a), and

(B) with respect to individuals only entitled to benefits under part B, by substituting an appropriate proportion of such rates (reflecting the relative proportion of payments under this title attributable to such part) for the payment rates otherwise established under subsection (a).

(4) The following requirements shall apply to eligible organizations with risk-sharing contracts under this section in the same manner as they apply to Medicare +Choice organizations under part C;

(A) Data collection requirements under section 1853(a)(3)(B).

(B) Restrictions on imposition of premium taxes under section 1854(g) in relating to payments to such organizations under this section.

(C) The requirement to accept enrollment of new enrollees during November 1998 under section 1851(e)(6).

(D) Payments under section 1857(e)(2).

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No. 98-1284

In the Supreme Court of the United States

OCTOBER TERM, 1998

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

GREGORIA GRIJALVA, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

REPLY BRIEF

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In the Supreme Court of the United States

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No. 98-1284

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

GREGORIA GRIJALVA, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

REPLY BRIEF

In *American Manufacturers Mutual Insurance Co.* v. *Sullivan*, 119 S. Ct. 977 (1999), this Court held that (1) private insurers in Pennsylvania's workers' compensation program are not state actors when they deny requests for medical services, *id.* at 985-989, and (2) beneficiaries in that program whose legal entitlement to particular requested benefits has not yet been determined lack a constitutionally protected property interest in those benefits for due process purposes, *id.* at 989-990. Because those holdings have a substantial bearing on the government action and due process issues in this case, a remand in light of *Sullivan* is appropriate. Moreover, because the issues in this case have been radically altered by comprehensive legislation reforming the Medicare practices respondents challenged, the judgments below should be vacated and the case remanded to the district court in any event.

1. This case, like *Sullivan*, turns on whether the decision of an otherwise private actor (an insurer or HMO) to deny a

request for medical services constitutes government action in the context of a comprehensive benefits scheme. Respondents nonetheless argue that a remand in light of *Sullivan* is unnecessary because *Sullivan* "does not modify [the] Court's prior holdings on state action." Br. in Opp. 14. *Sullivan*, however, clarifies the law—"clean[ing] up and rein[ing] in [the Court's] 'state action' precedent[s]," 119 S. Ct. at 991 (Ginsburg, J., concurring in part and concurring in the judgment)—in a way that demonstrates the errors in the lower courts' government-action analysis.

In particular, the courts below concluded that HMO treatment decisions constitute government action because there is a close nexus between HMOs and the government such that HMO decisions may fairly be treated as decisions of the federal government. The courts, however, found that nexus *not* because the government compels or influences HMO decisions, but instead because the "Secretary extensively regulates" HMOs, which must "comply with all federal laws and regulations"; because the Secretary pays HMOs "for each enrolled Medicare beneficiary (regardless of the services provided)"; because the Secretary can "overturn" HMO decisions challenged by the beneficiary; and because the "federal government has created the legal framework * * * within which HMOs" operate. Pet. App. 10a. *Sullivan*, however, holds that "[w]hether such a 'close nexus' exists * * * depends on whether the state 'has exercised coercive power or has provided such significant encouragement, either overt or covert, that the choice must in law be deemed to be that of the State.'" 119 S. Ct. at 986. Because neither court below found, and respondents nowhere argue, that the government exercises such power or provides such encouragement here (see Pet. 17-18 & n.6), the lower courts' rationale does not survive *Sullivan*.[1]

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[1] Respondents attempt to distinguish *Blum* v. *Yaretsky*, 457 U.S. 991, 1004, 1008-1009 (1982), by arguing that this case involves "coverage" decisions rather than medical judgments. Br. in Opp. 18. But they nowhere

Respondents assert that *Sullivan* is "vastly different" because "the state action finding" in this case is "predicated on a comprehensive federal statutory scheme establishing the Medicare program." Br. in Opp. 15. But the benefits scheme at issue in *Sullivan*—workers' compensation—was no less comprehensive or statutory than Medicare. Indeed, in *Sullivan* itself the court of appeals found state action because the private insurers were "providing public benefits which honor State entitlements," "fulfilling a uniquely governmental obligation under an entirely state-created, self-contained public benefit system." *Sullivan* v. *Barnett*, 139 F.3d 158, 168 (3d Cir. 1998).[2]

Alternatively, respondents rely on *West* v. *Atkins*, 487 U.S. 42 (1988). See Br. in Opp. 18-19. The courts below, however, did not rely on *West*, and *Sullivan* expressly rejected reliance on *West*. See 119 S. Ct. at 987-988. Respondents' new-found reliance on *West* thus makes reconsideration in light of *Sullivan* even more appropriate. Besides, *West* is plainly inapposite. In that case, the Court held that the conduct of a prison physician is state action because "the only medical care [the prisoner] could receive for his injury was that provided by the State." 487 U.S. at 55. If the physician "misused his power by demonstrating deliberate indifference to [the prisoner's] serious medical needs," the

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deny that each decision challenged by the named class members in this case is—like the decisions this Court held not to be state action in *Blum*—medical rather than legal in nature. See Pet. 17-18 & n.6.

[2] Likewise, *Sullivan* makes it clear that "extensive[] regulat[ion]," including the requirement that HMOs "comply with all federal laws and regulations," Pet. App. 10a, does not support a finding of government action, 119 S. Ct. at 986, where "the initiative" for the challenged conduct "comes from" the private party "and not from the [government]." *Jackson* v. *Metropolitan Edison Co.*, 419 U.S. 345, 357 (1974). And respondents nowhere explain why the fact that the Secretary pays the premium for the Medicare beneficiary to enroll in the HMO, Pet. App. 10a, should make a difference in the government-action inquiry, since the source of that payment neither encourages nor compels HMOs to deny treatment requests. See Pet. 17-18 & n.7.

Court reasoned, "the resultant deprivation was caused, in the sense relevant for state-action inquiry, by the State's exercise of its right to punish [the prisoner] by incarceration and to deny him a venue independent of the State to obtain needed medical care." *Ibid.*

Respondents attempt to bring this case within the reasoning of *West* by arguing that Medicare beneficiaries are "locked in" to and "dependent on" their HMOs for "coverage decisions." Br. in Opp. 19. That argument fails for three reasons. First, the government does not "deny [Medicare beneficiaries] a venue independent of the State to obtain needed medical care," *West*, 487 U.S. at 55; because the Medicare program is not needs-based, Medicare beneficiaries can and do seek medical treatment independent of the program. Indeed, Medicare beneficiaries whose treatment requests are denied not only can obtain treatment from non-HMO providers, but are entitled to have their HMOs pay for that treatment under Medicare if the Secretary determines the denial was improper. See 63 Fed. Reg. 35,108, 35,112 (1998) (adding 42 C.F.R. 422.566(b)(2)-(3), 422.618(a)(2) and (b)). Second, enrollment in an HMO (unlike treatment by a prison physician) is a matter of free choice for Medicare beneficiaries. They can choose among HMOs (where available) or reject HMO coverage altogether by electing fee-for-service coverage. Pet. 17. Third, Medicare beneficiaries may switch among HMOs, or return to traditional fee-for-service Medicare, at any time, effective the end of the month, until the year 2002; after that, they may switch during specified open season periods, or at any time under certain conditions, such as where an HMO fails to provide a required service. See Balanced Budget Act of 1997 (BBA), Pub. L. No. 105-33, § 4001, 111 Stat. 281, 283 (Section 1851(e)(2)(A) and (f)(1), to be codified at 42 U.S.C. 1395w-21(e)(2)(A) and (f)(1)); 63 Fed. Reg. at 35,072-35,073 (adding 42 C.F.R. 422.62(a)(3) and (b)(3)(i)(A)).

Finally, respondents are incorrect to characterize HMOs as "agents" of the government carrying out the "delegated"

function of making benefits determinations. Br. in Opp. 17, 19. Like the insurers in *Sullivan*, HMOs here neither act as government agents in pursuit of a public interest nor distribute public funds. Instead, HMOs responding to treatment requests by Medicare enrollees exercise their own private judgment as to whether they believe the requested treatment is necessary, reasonable, or otherwise within the scope of their obligation to provide—just as the private insurers did in *Sullivan*, and just as HMOs do with respect to enrollees whose premiums are not paid by Medicare. Of course, HMO determinations can be challenged through a dispute resolution mechanism established by the government. See BBA, 111 Stat. 294 (Section 1852(g)(4), to be codified at 42 U.S.C. 1395w-22(g)(4)); 63 Fed. Reg. at 35,111 (adding 42 C.F.R. 422.602(c)). But *Sullivan* makes it clear that the availability of review (an adjudication which "may properly be considered [government] action" and thus subject to due process limits) does not convert the private decision under review into government action as well. 119 S. Ct. at 987. To the contrary, because the initial private decision to grant or deny the beneficiary's request differs little from the decision any private actor confronting potential liability would make, the government's "role in creating, supervising, and setting standards" does not "differ in any meaningful sense from [its role in] the creation and administration of any [other] forum for resolving disputes." *Ibid.*[3]

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[3] Respondents also err in asserting (Br. in Opp. 17) that treating HMOs as private actors would create anomalous distinctions between fee-for-service and HMO-enrolled Medicare beneficiaries. A private physician who refuses to treat a patient on a fee-for-service basis because she believes that the service is not reasonable, necessary, or covered by Medicare surely is not a government actor; respondents have not offered any reason why the result should be different when the same decision is made for the same reasons within an HMO. HMO and fee-for-service Medicare beneficiaries, moreover, are in many ways treated alike. Just as an independent organization acting on behalf of the Secretary makes coverage determinations for fee-for-service treatments, so too such an

2. *Sullivan* also necessitates re-examination of the due process holdings below. In *Sullivan*, this Court held that an applicant for specific medical benefits under Pennsylvania's workers' compensation statute does not have a protected due process interest in those benefits before legal entitlement has been determined. 119 S. Ct. at 990. In particular, the Court explained, the statute there guaranteed payment not for all medical treatments, but rather only for medically necessary or appropriate services. The Court therefore held that beneficiaries under that statute do not have a protected interest in the requested benefits until medical necessity or appropriateness has been determined. *Ibid.* The Medicare statute similarly does not entitle beneficiaries to coverage for all medical treatments; instead, it provides coverage only for services that are, among other things, "reasonable and necessary." 42 U.S.C. 1395y(a)(1)(A).[4]

Of course, the respondents in *Sullivan* did not contend (and the Court therefore did not address) whether the beneficiaries might have a property interest in their claims for benefits, as distinct from the benefits themselves. 119 S. Ct. at 990 n.13. But respondents here likewise have not raised that argument, and neither court below analyzed the due process issue in those terms. An order granting the petition and remanding in light of *Sullivan* therefore is especially

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organization reviews all disputed HMO treatment decisions, and the provisions for further administrative consideration and judicial review of those decisions are similar as well. Compare 63 Fed. Reg. at 35,111 (adding 42 C.F.R. 422.592-422.608) with 42 C.F.R. 405.802-405.817 (1996).

[4] Respondents' claim that federal courts have "long recognized that due process principles apply to the Medicare package of health benefits" (Br. in Opp. 20) is unavailing. The only case from this Court that respondents cite (Br. in Opp. 5, 20), *Schweiker* v. *McClure*, 456 U.S. 188, 198 (1982), nowhere holds that mere applicants for Medicare benefits have a protected property interest in those benefits before legal entitlement is established. And the lower court decisions (Br. in Opp. 6, 9, 17, 20), *Kraemer* v. *Heckler*, 737 F.2d 214 (2d Cir. 1984); *Gray Panthers* v. *Schweiker*, 652 F.2d 146 (D.C. Cir. 1980); and *Martinez* v. *Richardson*, 472 F.2d 1121 (10th Cir. 1973), were decided without benefit of *Sullivan*.

appropriate. See also *id.* at 991 (Breyer, J., concurring in part and concurring in the judgment) (expressing the view that there may be "individual circumstances" under workers' compensation where "receipt of earlier payments" may give rise to a constitutionally protected property interest).[5]

3. The decisions below also should be vacated and the case remanded to the district court for reconsideration in light of the Balanced Budget Act of 1997 (BBA) and the Secretary's implementing regulations, 63 Fed. Reg. at 34,968. As we have explained (Pet. 20-26), those measures comprehensively reform the practices at issue in this case, replacing the prior program with the new Medicare+Choice program.

a. Attempting to minimize the significance of the BBA and the new regulations, respondents argue that they do not substantially alter the current controversy. Br. in Opp. 23. That argument is incorrect. The new Medicare+Choice program and implementing regulations address the very practices that respondents challenged in this lawsuit. They address the primary concern the district court identified by requiring HMOs to ensure that their notices of decision are *understandable*. Compare Pet. App. 46a-50a, 60-61a with Pet. 7, 11, 21 (explaining new provisions). They address the need for faster decisions, requiring HMOs to make decisions

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[5] As explained in the petition (at 18-19), the Ninth Circuit also erred by declining to give "substantial weight" to the Secretary's judgment regarding what procedures are necessary to ensure fundamental fairness in this context, in direct contravention of *Mathews* v. *Eldridge*, 424 U.S. 319, 349 (1976). And it likewise erred in approving a detailed injunction imposing new procedures, rather than remanding to the Secretary so that she could develop appropriate procedures through a fully participatory, public rulemaking. See Pet. 19. Respondents do not attempt to defend the latter aspect of the Ninth Circuit's decision. In attempting to defend the former, they argue (Br. in Opp. 20-21) that the Ninth Circuit did not refuse to give the Secretary's views "substantial weight," but instead declined to accord her views "great deference." Whether or not that is a distinction with a difference, respondents nowhere suggest that the Ninth Circuit accorded the Secretary's judgments *either* "substantial weight," as *Mathews* requires, *or* deference.

within 72 hours for urgently needed services, and within 14 days in ordinary cases; the regulations before the district court, in contrast, had a 60-day deadline and no expedition mechanism for urgent cases. Br. in Opp. 23 (conceding significance of new expedition mechanism); compare Pet. App. 51a-52a, 60a with Pet. 4, 8, 10-11, 21. And the BBA and the new regulations also address a host of related issues, including the qualifications of decisionmakers, pre-termination review for in-patient hospital care, and protection of medical professionals who assist beneficiaries in processing appeals. Pet. App. 49a, 62a; Pet. 8, 11-12, 21 & n.11.

Respondents argue, however, that their challenge is not moot because the new provisions "do not satisfy the requirements of the district court's remedial order." Br. in Opp. 22. But it is not compliance with the district court's order that renders the appeal moot. It is the fact that the BBA and implementing regulations have *replaced* the program respondents challenged and thus have so "altered" the circumstances of the dispute that the case (if it remains a live controversy at all) now "present[s] a substantially different controversy from the one the [courts below] originally decided." *Northeastern Fla. Chapter of the Associated Gen. Contractors* v. *City of Jacksonville*, 508 U.S. 656, 662 n.3 (1993); *id.* at 670-671 (O'Connor, J., dissenting); Pet. App. 66a (district court's recognition that "on appeal much of the March 3, 1997 Order might be moot" because of "efforts on the part of state and federal legislatures [to] address[] the same issues addressed by [the district] [c]ourt").

In fact, respondents' complaints about the new Medicare+ Choice program—that it reduces the time during which HMOs must issue decisions in non-urgent cases from 60 days to 14 days rather than to 5 days, as the district court ordered, and that it requires pre-termination hearings only with respect to in-hospital treatment rather than for all services falling in the vague category of "acute care," Br. in Opp. 23; Pet. 22 n.12—only underscore the changed nature of the dispute. The district court may have concluded that two

months even in non-urgent cases was so excessive as to violate due process, but it has not reached the same conclusion with respect to the two-week period under the new program. Indeed, unless the district court were to conclude that the differences between 14 days and 5 days, and between so-called "acute care" and "in-hospital" treatment, are of constitutional dimension—a dubious proposition respondents nowhere advance—then the BBA and implementing regulations leave no constitutional deficiency to redress.[6]

b. Alternatively, respondents argue (Br. in Opp. 26) that the Secretary may obtain relief from the district court by filing a motion under Federal Rule of Civil Procedure 60(b). This Court, however, has never suggested that a Rule 60(b) motion is an appropriate substitute for vacatur and remand when a new law moots lower court decisions that otherwise warrant this Court's review. To the contrary, the Court's practice has been to vacate the judgment of the court of appeals and remand the case to that court with directions to (1) vacate the district court judgment and (2) remand to the district court for reconsideration in light of the intervening legislation. See Pet. 23 (citing, *inter alia*, *Calhoun* v. *Latimer*, 377 U.S. 263, 264 (1964) (per curiam); *Heckler* v. *Lopez*, 469 U.S. 1082 (1984) (mem.)); see also *United States Dep't of the Treasury* v. *Galioto*, 477 U.S. 556, 559-560 (1986); *United States* v. *Chesapeake & Potomac Tel. Co.*, 516 U.S.

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[6] As explained in the petition (at 23-24 & n.13), the BBA also eliminates the subject matter—risk contracts under 42 U.S.C. 1395mm(g)—on which the district court purported to act, and renders inoperative the statutory language in 42 U.S.C. 1395mm(c)(1), upon which both courts below relied. Respondents dispute that, arguing that those provisions have not been repealed. Whether or not those provisions have been repealed, they have been rendered inoperative with respect to the HMO risk contracts at issue here. The Secretary's authority to enter into such risk contracts under Section 1395mm(g) has been withdrawn; no Section 1395mm(g) risk contracts remain in force; and Section 1395mm(c)(1) has no effect here because it applies to contracts under Section 1395mm(g) but not to contracts under Medicare+Choice. See Pet. 9-10 & n.2.

415, 416 (1996) (per curiam).[7] That course is especially warranted here because the Ninth Circuit's decision resolves important issues of constitutional law for about one-fifth of the nation's populace, profoundly affects an important national program involving hundreds of HMOs and millions of Medicare beneficiaries, and therefore plainly warrants certiorari, especially in light of *Sullivan*.

c. Finally, respondents (Br. in Opp. 26-27) fault the Secretary for not suggesting mootness to the court of appeals. The short answer is that, at the time the case was before the Ninth Circuit panel, the new Medicare+Choice program had not been implemented, and the program and practices that respondents challenged were still in place. Because those circumstances have since changed, vacatur and remand is now appropriate.

* * * * *

For the foregoing reasons and those stated in the petition, it is respectfully submitted that the petition for a writ of certiorari should be granted, the judgment of the court of appeals vacated, and the case remanded to the court of appeals with directions to (1) vacate the judgment of the district court and (2) remand the case to the district court for further consideration in light of *American Manufacturers Mutual Insurance Co.* v. *Sullivan*, 119 S. Ct. 977 (1999); Sections 4001 and 4002 of the Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 275-330; and the implementing regulations of the Secretary of Health and Human Services.

SETH P. WAXMAN
Solicitor General

APRIL 1999

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[7] *Agostini* v. *Felton*, 521 U.S. 203 (1997) (see Br. in Opp. 26) did not involve, and nowhere discusses, the appropriate disposition of appeals mooted by legislation pending review; it merely discusses the standards for Rule 60(b) motions. *Standard Oil* v. *United States*, 429 U.S. 17 (1976) (per curiam), addresses only the propriety of a Rule 60(b) motion based on new evidence discovered after the judgment was affirmed on appeal.

Supreme Court, U.S.
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IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1998

DONNA E. SHALALA,
SECRETARY OF HEALTH AND HUMAN SERVICES,
Petitioner,

v.

GREGORIA GRIJALVA, *et al.*,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

BRIEF OF AMICUS CURIAE AMERICAN ASSOCIATION OF HEALTH PLANS IN SUPPORT OF PETITIONER

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INTEREST OF THE AMICUS

Amicus curiae respectfully submits this brief in the support of Petitioner. Amicus curiae, the American Association of Health Plans, Inc. ("AAHP"), is a non-profit trade association representing approximately 1,000 managed care companies, many of whom are currently involved in the Medicare program throughout the United States. AAHP's principal purpose as a trade association is to foster, encourage and assist development of an organized, pre-paid healthcare system as an alternative to other arrangements for the delivery of healthcare services. AAHP's brief focuses on two of the questions presented: Issue 1 (whether the denial by private health maintenance organizations ("HMOs") of healthcare services under the Medicare Program constitutes government action) and Issue 3 (whether the Court should vacate the judgments below in light of the new legislation and regulations governing Medicare). AAHP also addresses the impact that the decision below will have if the Court does not vacate it.[1]

By participating in this action, AAHP seeks to protect its members' rights. AAHP is concerned that, if the lower court judgments in this case are upheld, the imposition of "government actor" status on private healthcare companies could have a far-reaching impact on all managed care organizations who participate in publicly-funded programs. The judgments will impose costly administrative requirements on Medicare HMOs in all aspects of their operations. In addition, as a result of the broad

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[1] Pursuant to Supreme Court Rule 37.6, AAHP states that no counsel for a party authorized this brief in whole or part; and that no person or entity, other than the amicus and its counsel, contributed monetarily to the presentation or submission of this brief. The consents to the filing of this amicus brief in this proceeding have been filed with the Clerk.

application of the government action doctrine by the courts below, the decisions in this case are likely to be the basis of even more attenuated claims of government action in the future. Indeed, at least one Medicaid healthcare provider has already cited the district court's decision as a basis for challenging the non-renewal of contracts. The decisions will also inevitably expand the grounds for beneficiary litigation challenging medical decisions, benefit changes, coverage determinations and review procedures.

In addition, the court of appeals' decision will likely have an adverse impact on the new "Medicare+Choice" program and Medicare beneficiaries. The expansive application of the government action doctrine to private healthcare companies will discourage participation in the Medicare+Choice program by health plans and their affiliated providers.

STATEMENT OF CASE

This action involves the coverage of medical care by HMOs under the Medicare program. Respondents sought declaratory and injunctive relief against Petitioner, the Secretary of the Department of Health and Human Services ("the Secretary"), for allegedly failing "to enforce due process requirements," and "to monitor HMO denials of medical services to enrolled Medicare beneficiaries." *Grijalva v. Shalala*, 152 F.3d 1115, 1117 (9th Cir. 1998).

At the time of the district court litigation, HMOs participated in the Medicare program under "risk-sharing" agreements pursuant to 42 U.S.C. §1395mm(g). Congress has since abolished that program and replaced it with the new Medicare+Choice program. Under the former risk contracts, HMOs were paid a fixed monthly

payment for each Medicare beneficiary who chose to enroll in the HMO. The fixed monthly premium rates were based, in large part, on the fee-for-service costs necessary to provide the basic Medicare benefits. Risk-sharing HMOs were also required to submit an "adjusted community rate" ("ACR") to the Secretary each year. The ACR represents the amount the HMO would charge in the open market for a package of basic Medicare benefits. 42 U.S.C. §1395mm(e)(3). If the ACR for the basic Medicare benefits was below the monthly rate, an HMO could either refund the difference to the government or provide "additional benefits" to beneficiaries valued at the difference between the HMO's ACR and the Medicare premium. 42 U.S.C. §1395mm(g)(2).[2] Traditionally, HMOs added benefits and reduced or eliminated any co-payment due from the beneficiary. Accordingly, Medicare risk-sharing HMOs generally provided beneficiaries with the basic Medicare benefits under the statute plus additional benefits at no additional charge to the government or the beneficiary.

The Secretary did not adjust monthly payments based on the services actually utilized by beneficiaries. Rather, the risk-sharing Medicare HMOs bore the risk that increased patient needs and attendant costs could exceed the fixed monthly payments received for each Medicare beneficiary. These risk-sharing components of the Medicare contracts were similar to HMO coverage purchased by individuals or employers for their employees in the commercial market.

Respondents below alleged that Petitioner failed to enforce adequately her statutory and due process obliga-

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[2] Under the risk-sharing contracts, HMOs were also permitted to provide additional benefits for a premium charged to Medicare enrollees subject to the express approval of the Health Care Financing Administration ("HCFA"). *Id.* at §1395mm(c)(2).

tions under the Medicare statute and regulations when HMOs denied coverage for claims submitted by Medicare beneficiaries. The district court held that Respondents' "claim hinge[d] on whether HMO denials of service constitute[d] state action." *Grijalva v. Shalala*, 946 F. Supp. 747, 751 (D. Az. 1996). Finding state action, the district court granted Respondents' motion for summary judgment, ruling that the notices of denial of coverage were difficult to understand. The court issued an injunction specifying the type of written notice required for coverage denials and the time requirements necessary to comport with the due process mandates of the Fifth Amendment. The injunction also mandated that the Secretary monitor and investigate compliance with the court's notice requirements, and barred the Secretary from renewing contracts with any HMO that did not comply with the provisions of the court's order. The Court of Appeals for the Ninth Circuit upheld the district court's decision, relying heavily on the district court's reasoning.

On August 5, 1997, while the appeal was pending, Congress passed the Balanced Budget Act of 1997 ("BBA"), Pub. L. No. 105-33, Sec. 4001-4002, 111 Stat. 275-330. The BBA eliminated all risk-sharing contracts and thereby effectively repealed Section 1395mm(g), the statutory provision at issue in this case. Congress replaced risk-sharing contracts with the Medicare+Choice program. The BBA also eliminated the Secretary's authority to renew risk-sharing contracts as of January 1, 1999. Pursuant to the new law, the Secretary promulgated regulations to implement the new Medicare+Choice program.

Petitioner filed her Writ for Petition of Certiorari on February 11, 1999. Petitioner requested that the Court hold the Petition until the Court issued its opinion in

American Manufacturers Mutual Insurance Co., et al. v. Sullivan, et al., 526 U.S. ____, No. 97-2000, (March 3, 1999) (slip op.). Now that the Court has issued its ruling in *Sullivan*, the Court should grant Petitioner's writ. The Court should vacate the court of appeals' decision, direct the court of appeals to vacate the district court's injunction, and remand the case to the district court for consideration of the Respondents' claims in light of the *Sullivan* decision, the passage of the BBA and the regulations promulgated thereunder.

SUMMARY OF ARGUMENT

1. The Court Of Appeals' Ruling Is Inconsistent With The *Sullivan* Decision

This Court's recent opinion in *Sullivan* rejected the very factors that the lower courts in the instant case employed to evaluate potential government action, including "joint participation" in a program and extensive government regulation. *Sullivan*, slip op., at 16. Moreover, as this Court reaffirmed in *Sullivan*, private decisions regarding medical benefits, as are at issue here, are not the type of action traditionally taken by the government. Rather, such action is traditionally "made by concededly private parties, and 'turns on . . . judgments made by private parties' without 'standards established by the State.' " *Sullivan*, slip op., at 11 (quoting *Blum v. Yaretsky*, 457 U.S. 991, 1008 (1982)). Accordingly, the court of appeals decision below, finding that an HMO assumes the role of a government actor when it denies coverage of a medical benefit for a Medicare beneficiary, runs afoul of this Court's decision in *Sullivan*.

2. HMO Actions That Violate The Medicare Statute Do Not Constitute Government Action

Respondents contend below that the HMOs' written coverage determinations did not provide the procedural safeguards mandated by the Medicare statute and regulations, and that the Secretary failed to enforce those safeguards. The courts have previously held that actions by a private party in violation of statutory authority or administrative regulations do not constitute government action. *Starnes v. Capital Cities Media, Inc.*, 39 F.3d 1394, 1397 (7th Cir. 1994) (citing *Lugar v. Edmondson Oil Co.*, 457 U.S. 922, 937 (1982)). As this authority demonstrates, the HMO coverage decisions at issue do not constitute government action to the extent that HMOs acted outside of the statutory and regulatory requirements imposed by the Medicare Act.

3. The Decisions Will Have Unfavorable And Far-reaching Effects

If the court of appeals' holding in this case is permitted to stand, serious adverse consequences will result. If the requirements for participation in the Medicare+Choice program are to be dictated, in part, by the application of the government action doctrine by individual courts on an *ad hoc* basis, many HMOs will be discouraged from participating or from continuing to participate in such an unsettled regulatory environment.

The decision below also is likely to spawn litigation by providers as well as beneficiaries. Providers already have argued, based on the decisions below, that HMOs act as the government's proxy when choosing the providers with whom they wish to contract for purposes of Medicaid. *Catanzano v. Wing*, 103 F.3d 223, 227 (2d Cir. 1996).

That case demonstrates the breadth of the decisions below and the seemingly limitless application of those decisions unless they are vacated.

4. The Balanced Budget Act Of 1997 Mandates The Case Be Vacated And Remanded

In August 1997, Congress passed the Balanced Budget Act ("BBA"). This Act abolished "risk-sharing" HMOs in the Medicare Program as of January 1, 1999. Moreover, the BBA established enhanced notice and appeal opportunities to beneficiaries under the Medicare+Choice program. As a result, the court of appeals based its decision on a program that no longer exists. The BBA's abolishment of the statutory basis for the district court and the court of appeals' decisions mandates that this case be remanded to consider the BBA and the Secretary's new regulations.

REASONS FOR GRANTING THE PETITION

I.

THE COURT OF APPEALS' RULING SHOULD BE VACATED IN LIGHT OF THIS COURT'S RECENT RULING IN THE *SULLIVAN* CASE.

The lower courts' decisions are at odds with the opinion issued by this Court on March 3, 1999, in *American Manufacturers Mutual Insurance Company, et al. v. Sullivan,* 526 U.S. ___ , No. 97-2000 (March 3, 1999) (slip op.). In *Sullivan,* this Court rejected the Third Circuit's application of the state action doctrine to private insurers seeking utilization review of treatment requests for individuals receiving workers' compensation benefits. That ruling is controlling over the instant case and calls for the Court to vacate the court of appeals' decision here.

The issues in both cases are nearly identical. In *Sullivan*, the Court considered "whether a *private insurer's* decision to withhold payment for disputed medical treatment may be fairly attributable to the State so as to subject insurers to the constraints of the Fourteenth Amendment." *Sullivan*, slip op., at 10 (emphasis in original). Similarly, in the instant case, one of the issues before the Court is:

> [w]hether the decision by a Section 1395mm(g) HMO to deny an enrolled Medicare beneficiary's request for health services constitutes government action subject to the requirements of the Due Process Clause of the Fifth Amendment.

Pet. Br. at I. Both cases turn on whether health benefits coverage determinations by private entities, in one case workers' compensation insurers and in the other Medicare HMOs, constitute government action. The Court in *Sullivan* answered this question "no." *Sullivan*, slip op., at 10.

The courts below failed to apply the appropriate standards for analyzing claims of government action by private entities. In a series of decisions over the past thirty years, this Court has established the proper analytical framework and standards to determine whether it is appropriate to impose on federal and state officials responsibility for the conduct of private parties. The benchmarks for establishing government action are not easily met in order to protect private citizens' actions against the unfair imposition of constitutional restraints, and to avoid "imposing on the states, its agencies or officials, responsibility for conduct which they cannot fairly be blamed." *Lugar*, 457 U.S. at 936-937.

As recently reaffirmed in *Sullivan*, this Court established two prerequisites for imposing due process requirements on private entities acting as a proxy for the

government. First, the challenged activity must be "caused by the exercise of some right or privilege created by the State or by a rule of conduct imposed by the [government] or by a person for whom the [government] is responsible." *Sullivan*, slip op., at 8 (quoting *Lugar*, 457 U.S. at 937); *also see*, *Flagg Bros., Inc. v. Brooks*, 436 U.S. 149, 156 (1978). Second, "the party charged with deprivation must be the person who may fairly be said to be a [government] actor." *Ibid.* In the case before the Court, the Medicare statute established the rights at issue. Accordingly, Respondents likely satisfy the first prong of the test to determine government action. Respondents fail, however, to fulfill the second prong—identifying a party that is acting as a proxy for the federal government.

The court of appeals based its finding of government action on the contention that risk-sharing HMOs and the Secretary "jointly participated" in the Medicare program. *Grijalva*, 152 F.3d at 1119-1120. The court of appeals' reliance on the "joint participation" theory is misplaced. In *Sullivan*, this Court reversed a Third Circuit decision that relied on the same joint participation theory as relied upon by the court of appeals in the instant case. The Third Circuit ruled that the Pennsylvania workers' compensation system "inextricably entangles the insurance companies in a partnership with the Commonwealth such that they become an integral part of the state in administering the statutory scheme." *Sullivan v. Barnett*, 139 F.3d 158, 170 (3d Cir. 1998), *rev'd*, 526 U.S. ___ (1999). The *Sullivan* Court rejected "joint participation" between insurance companies and the State as a basis for establishing government action. *Sullivan*, slip op., at 16-17.

The mere invocation of "joint participation" is insufficient to establish government action. Rather, the courts

must assess the facts and the specific allegations made by the plaintiff that give rise to the claim. *Ibid.* The courts determine whether the government "has exercised coercive power or has provided such significant encouragement, either overt or covert, that the choice must in law be deemed to be that of the State." *Id.*, slip op., at 10 (quoting *Blum*, 457 U.S. at 1004). This Court recognizes that action taken with "mere approval or acquiescence" of the government is not sufficient to create government action. *Ibid.*

The court of appeals below identified five facts in support of its finding of joint participation between the Secretary and risk-sharing HMOs. None of these facts, however, when analyzed in light of this Court's prior decisions, support the lower court's finding that Medicare HMOs were acting as a proxy for the Secretary.

First, the court of appeals stated that the government regulates HMOs' activities as they apply to Medicare beneficiaries, especially benefit coverage determinations. *Grijalva*, 152 F.3d at 1120. This Court has consistently held, however, that extensive regulation of an industry does not render private actions by members of that industry government action subject to constitutional restrictions. *Sullivan*, slip op., at 10; *Blum*, 457 U.S. at 1004; *Jackson v. Metropolitan Edison Co.*, 419 U.S. 345, 350 (1974). If simple imposition of government regulations created government action, then virtually every action by an HMO would be classified as such. HMOs are regulated under federal and state law. Moreover, many healthcare plans provided by HMOs are provided through employer groups and are governed by the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. §§1001, *et seq.* (1999). These provisions frequently impose mandates that include providing certain appeal rights to subscribers to protest any medical coverage

determinations made by an HMO. *See, e.g.*, ERISA, 29 U.S.C. §1133 (1999); *see also*, Md. Code Ann., Ins. Art §15-10A-02 (1997 & Supp. 1998). If each of these requirements transformed HMO coverage decisions into government action, then little of what HMOs do would escape the due process requirements of the Fifth or Fourteenth Amendment. As the Court made clear in *Sullivan*, such expansive applications of the government action doctrine are disfavored.

Second, the courts below relied on the fact that the Secretary issued regulations regarding internal appeal processes under the Medicare program to demonstrate joint participation. *Grijalva*, 152 F.3d at 1120. Yet, this is no different from the prior factor–there is a substantial regulatory framework governing Medicare. The Court has previously held that this type of regulatory framework, and the fact that participants must operate within that framework, does not convert otherwise private action into government action. *Blum*, 457 U.S. at 1000. Moreover, the internal appeal processes are common to HMOs and not unique to Medicare. In private contracts, HMOs often provide similar, if not identical, internal appeals processes. Accordingly, this fact indicates traditional private action, not action attributable to the sovereign.

Third, the courts below found that the Secretary has delegated medical coverage decisions to HMOs. *Grijalva*, 152 F.3d at 1120. The Secretary, however, could not delegate these decisions because they were never hers to make. The Medicare statute specifically prohibits the "exercise [of] any" governmental "supervision or control over the practice of medicine or the manner in which medical services are provided." 42 U.S.C. §1395. Given this prohibition, the independent determinations of medical coverage by HMOs participating in the Medicare program cannot fairly be attributed to the Secretary.

Moreover, in *Sullivan*, the Court rejected this precise argument as an overly simplistic approach to addressing government action.

> Such permission of a private choice cannot support a finding of state action. As we have said before, our cases will not tolerate 'the imposition of Fourteenth Amendment restraints on private action by the simple device of characterizing the State's inaction as authorization or encouragement.'

Sullivan, slip op., at 12 (quoting *Flagg Bros.*, 436 U.S. at 164-165). Neither Respondents nor the courts below have demonstrated that HMOs fail to exercise independent judgment when denying claims based on issues of medical appropriateness, necessity or coverage.

To be considered government action, these medical coverage decisions must be both traditionally and exclusively a government function. *Blum*, 461 U.S. at 1005; *Jackson*, 419 U.S. at 353; *see*, *Flagg Bros.*, 436 U.S. at 157-161. Such exclusive functions would include conducting elections, *Edmonson v. Leesville Concrete Co.*, 500 U.S. 614, 624 (1991), exercising the power of eminent domain, *Jackson*, 419 U.S. at 352-354, or governing a city or a town, *Marsh v. Alabama*, 326 U.S. 501 (1946). Decisions as to the medical appropriateness of care are not a "traditional government function," giving rise to government action. *Edmonson*, 500 U.S. at 622.

To the contrary, HMOs, not the government, make determinations every day regarding the medical appropriateness and necessity of medical treatment. HMOs routinely make these decisions in commercial relationships as well as government-sponsored health benefits programs. As the Court pointed out in *Sullivan*, this function is a "traditionally private prerogative" that, no matter how it is characterized, does not constitute government action. *Sullivan*, slip op., at 15. Simply put, the "day-to-

day" determinations of healthcare benefits is not a function that is "traditionally the exclusive prerogative of the state." *Blum*, 457 U.S. at 1005 (citing *Jackson*, 419 U.S. at 353).

Fourth, the court of appeals found that HMOs' coverage decisions were government action based, in part, on the fact that the government "pays HMOs for each enrolled Medicare beneficiary . . ." *Grijalva*, 152 F.3d at 1120. Yet, the identity of the payor of benefits is not germane to the issue of whether or not risk-sharing HMOs under the Medicare program are government actors. As the Court affirmed in *Sullivan*, there are two prerequisites for determining when private action constitutes government action. The first factor is whether the right or privilege at issue is created by the government. *Sullivan*, slip op., at 8; *also see*, *Lugar*, 457 U.S. at 937. The fact that Medicare is federally funded may satisfy this factor. This funding, however, does not affect the second factor, whether the private party can be considered a "government actor." *Blum*, 457 U.S. at 1011. As the Court held in *Blum*, the funding of a program does not affect whether or not the actions of a private party are considered government acts. *Ibid.*

Finally, the court of appeals found that the fact that Medicare beneficiaries can appeal HMO service denials directly to the Secretary who "has the power to overturn the HMO's decision" was pertinent to the government action analysis. *Grijalva*, 152 F.3d at 1120. To the contrary, if the mere fact that private decisions by HMOs can ultimately be appealed to and overturned by some government authority, administrative body or court was attributable to the government, then almost all coverage decisions by HMOs constitute government action. Coverage decisions can almost always be appealed to various state administrative agencies, state courts, or federal

courts. Indeed, this Court did not find government action in the *Sullivan* case even though employees could appeal the workers' compensation insurance determinations to a workers' compensation administrative law judge for *de novo* review. *Sullivan,* slip op., at 5. Similarly, the availability of an appeal to the Secretary of an initial coverage determination by an HMO does not render the HMO's original determination government action.

In sum, the facts relied on by the court of appeals in its decision do not justify the conclusion that private determinations as to medical coverage by HMOs constitute government action. Rather, decisions regarding medical coverage have been traditionally private action. In fact, the very Medicare statute that the court of appeals relied on for finding government action specifically prohibits the Secretary from supervising or controlling such decisions.

II.

HMOs' PRIVATE ACTIONS, TO THE EXTENT THEY VIOLATE THE MEDICARE STATUTE AND REGULATIONS, DO NOT CONSTITUTE GOVERNMENT ACTION

The courts have recognized that a state or federal agency cannot be held liable for actions of a private party in violation of that agencies' regulations or authorizing statutes. *Starnes v. Capital Cities Media, Inc.,* 39 F.3d 1394, 1397 (7th Cir. 1994) (citing *Lugar,* 457 U.S. at 937) ("Misuse of state law is not, however, state action for the purposes of the Fourteenth Amendment."); *cf., Flagg Bros.,* 436 U.S. at 166 (a state's refusal to act does not constitute state action under the Fourteenth Amendment). By its very definition, private actions taken in violation of statutory or regulatory mandates are not undertaken at the "coercive power" or through "significant encouragment" of state or federal agencies. *Blum,* 457 U.S. at 1004.

Yet, in essence, that is what Respondents alleged in their complaint below. Respondents complained that HMOs were not abiding by the Medicare statute and the Secretary's regulations in providing benefits, notice of denials and other procedural safeguards. According to the court of appeals, Respondents sought declaratory injunctive relief against the Secretary for failing "to enforce due process requirements," and "to monitor HMOs and ensure that HMOs provided Medicare covered benefits." *Grijalva*, 115 F.3d at 1117. The actions complained of by Respondent cannot, by definition, constitute government action subject to constitutional mandates of due process.[3] HMOs allegedly acting in violation of the statutory and regulatory mandates under the Medicare program can hardly be deemed as acting as a proxy for the Secretary.

III.

PERMITTING THE COURT OF APPEALS' THEORY OF GOVERNMENT ACTION TO STAND WILL HAVE FAR-REACHING UNFAVORABLE IMPLICATIONS

If the court of appeals' holding in this case is permitted to stand, serious adverse consequences will result. The court of appeals' decision below is an expansive and unwarranted application of the government action doctrine. In addition, the injunction is nationwide resulting from a national class action. The variegated potential implications of the decisions below alone warrant close examination of the Petition in this case.

The court of appeals' decision discourages HMO participation in Medicare. Medicare+Choice plans contracted with the Secretary based on the understanding they were subject to the statutory and regulatory requirements of the Medicare program. The decisions below threaten to

[3]The only exception to this is Respondents' complaint that the regulatory appeal process for denial of "emergency" benefits is not sufficiently expedited to afford beneficiaries due process.

scuttle the regulatory requirements developed by the Secretary and augment or replace those standards with others developed by the courts on an *ad hoc* basis pursuant to the government action doctrine. Current Medicare+Choice participants are left uncertain as to the regulatory framework in which they are operating. Prospective Medicare+Choice plans must decide whether to join the program in the face of an unsettled regulatory scheme that, according to the court of appeals' decision, can be changed by claims of due process violations by Medicare beneficiaries.

In addition to this uncertainty, each additional due process requirement imposed by the courts will create additional financial and administrative burdens on HMOs, further limiting the willingness of HMOs and other private organizations to participate in the Medicare+Choice program. At a minimum, these increased costs could result in decreased benefits to Medicare beneficiaries. A decrease in participation by HMOs in the Medicare+Choice program will reduce the choice of plans and potentially limit the benefits available to beneficiaries.

The remedies mandated by the district court will also adversely impact the Medicare program, beneficiaries and participating HMOs. The district court's injunction requires HMOs to give beneficiaries written notice whenever a coverage determination results in a service or referral requested by a healthcare provider or enrollee being denied, or an ongoing course of treatments being reduced or terminated. Pet. Br. at 7, Pet. App. at 60a. The injunction in place appears to require HMOs to provide notice of each reduction or termination of a health benefit, even if ordered by the beneficiary's healthcare provider because his or her condition has improved to the degree that the benefit is no longer

necessary. Requiring notice in such situations will only serve to confuse beneficiaries and burden HMOs.

The injunction may also require a similar notice if an HMO changes its Medicare benefits. HMOs currently provide services in addition to the standard benefits mandated under the Medicare Act. HMOs provide these services based upon a comparison of the Medicare rates to the costs of such benefits in the commercial market. An HMO may alter its benefits in any given year to reflect the commercial market realities. Under the injunction, it is unclear whether an HMO can effectuate a reduction or elimination of any benefit without a due process notice and hearing.

Equally alarming is the district court mandate prohibiting the Secretary from renewing contracts with HMOs that fail to comply the court's notice requirements. *Grijalva*, 946 F. Supp. at 760. As explained above, the notice requirements imposed by the district court are vague and flawed. HMOs may fail to comply with the notice provisions, not out of neglect or other wrongdoing, but rather because of misunderstandings as to the notice requirements. The draconian sanction of non-renewal of contracts imposed by the district court, if upheld, will create a serious disincentive for HMOs currently participating in the program as well as for those plans considering future participation in Medicare+Choice. Moreover, once a contract is not renewed, the HMO is precluded from participating in the Medicare Program for five years. 42 U.S.C. §1395w-27(c)(4).

The court of appeals' decision below will also undoubtedly become a launching pad for new litigation to challenge Medicare+Choice HMOs' actions in the courts. Providers will now argue that HMOs are acting as a proxy for the Secretary when they determine the providers with

whom they wish to contract. As such, providers will contend that they are all entitled to due process before HMOs can decide not to enter into a contract or renew a contract with the provider. Indeed, at least one Medicaid provider has already cited the decisions below for the proposition that a health plan contracting with a state Medicaid program is a government actor that must provide procedural due process before deciding not to renew a provider's contract. *Catanzano*, 103 F.3d at 227.

In sum, it is foreseeable that decisions other than coverage determinations, e.g., decisions about administrative policy, changes in benefit packages, exiting a service area or terminating provider contracts, could also implicate substantive or procedural due process rights under the lower courts' decisions. The outgrowth of those decisions may very well circumvent the balance of interests established under the BBA. Constitutionalizing the private relationship between providers and HMOs also disturbs an area traditionally defined by contract, and to some degree, by statute and regulation.

IV.
THE BALANCED BUDGET ACT OF 1997 MANDATES THE CASE BE VACATED AND REMANDED

In August 1997, Congress passed the BBA. This Act abolished risk-sharing HMOs in the Medicare Program as of January 1, 1999, and effectively repealed the statutory provision at issue in this case. The BBA, in addition to eliminating risk-sharing HMOs, established enhanced regulations governing the notice and appeal opportunities provided to beneficiaries by HMOs participating in the Medicare+Choice program. In short, the BBA and the regulations promulgated thereunder addressed the concerns raised by the courts below. As a result, the deci-

sions below must be remanded to address the notice and appeal issues under the new statutory and regulatory framework.

The BBA and the regulations promulgated thereunder, now require, *inter alia*, understandable written notices of decisions, 111 Stat. 293 (Section 1852(g)(1); 42 C.F.R. 422.568(d)); medical necessity decisions made by qualified medical personnel, 111 Stat. 293 (Section 1832(g)(2)(B); 42 C.F.R. 422.590(g)(2)(B)); and timely initial and reconsideration decisions. 111 Stat. 293-294 (Section 1852(g)(2) and (3); 42 C.F.R. 422.568(a), 422.572, 422.590(a)-(d)). These are precisely the issues that Respondents included in their complaint and that the district court addressed in its injunction.

These new provisions supersede the regulatory scheme that existed for risk-sharing HMOs and therefore eradicate the need for injunctive relief in this case. As this Court and the Petitioner have rightly stated, the law has " 'been sufficiently altered' pending appeal 'so as to present a substantially different controversy than the one the [lower courts] originally decided.' " Pet. Br. at 35 (quoting *Northeastern Fla. Chapter of the Associated Gen. Contractors v. City of Jacksonville*, 508 U.S. 656, 662 n.3 (1993); *id.* at 670-671 (O'Connor, J., dissenting)). The BBA's abolishment of the statutory basis for the district court and court of appeals' decisions, coupled with this Court's decision in *Sullivan*, mandate that the judgment of the court of appeals be vacated and remanded to the district court.

CONCLUSION

The courts below improperly held that coverage determinations made by Medicare HMOs constitute government action. Consistent with the *Sullivan* decision, neither the Respondents nor the court of appeals can transform these private decisions into federal action. Accordingly, the Court should grant the Petition for Writ of Certiorari, vacate the judgment of the court of appeals, direct the court of appeals to vacate the judgment of the district court and remand the case to the district court for further review in light of the *Sullivan* decision, the BBA and its implementing regulations.

Respectfully submitted,

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